Diet Quality Improvement in Weight Loss Trials

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Diet quality, the healthfulness of the diet, has been shown to relate to both cardiometabolic risk factors and disease. As such, it may be a promising target in interventions among those with or at risk for chronic disease. However, research is needed to determine the ability of current behavioral interventions to affect diet quality.

This dissertation first systematically reviewed behavioral weight loss interventions which measured changes in diet quality in order to assess the methodological approaches taken by researchers. Articles were identified using PubMed, Ebscohost CINAHL, Ovid APA PsycINFO, Embase.com, Scopus, and Web of Science (Manuscript 1). Data from the SMARTER randomized controlled trial (N=502) was also used to examine the effect of a mobile health intervention on diet quality improvements and the relationship between diet quality improvements and weight loss (Manuscript 2), and evaluated the relationship between perceived and calculated diet quality and diet quality improvement (Manuscript 3). Manuscript 2 used the Population Ratio Method and bootstrapping to compare confidence intervals between intervention and comparator groups and by weight loss status subgroups. Manuscript 3 used the concordance correlation coefficient and Bland-Altman plots.

The systematic review revealed few studies used preferred methods of diet quality calculation. Dietary improvements were small with little supporting evidence for incorporating specific behavioral strategies. In Manuscript 2, over follow-up, meaningful improvements in diet quality did not occur with the provision of feedback to dietary self-monitoring or with self-

monitoring alone. However, improvements in diet quality were observed among those experiencing clinically meaningful weight loss. Manuscript 3 revealed misalignment between perceived and calculated diet quality, mostly due to better perceived diet quality. Misalignment was more pronounced when assessing change in diet quality.

Our analyses suggest more investigation and standardized reporting of whether meaningful diet quality changes are occurring in weight loss seeking adults undergoing behavioral treatment is needed. In SMARTER dietary improvements were not apparent overall, but were in adults with clinically relevant weight loss. Future studies should seek to improve on this success by identifying behavior change techniques supportive of diet quality improvement possibly including those targeted at misperception of dietary change.

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Preface

Research reported in this dissertation was supported by the National Heart, Lung, And Blood Institute under Award Number F31HL156278 (Cheng) and HL131583 (Burke). The content does not necessarily represent the official views of the National Institutes of Health. We would like to acknowledge the SMARTER study participants for their time and efforts.

This dissertation was completed despite significant delays caused by Giggy and Purr Purr who sat on my lap, sat on the back of my chair, sat on the arm of my chair, sat on my textbooks, sat on my notebooks, sat in front of my keyboard, and sat on my hand as I was typing. Generally, though, they are good kitties.

My interest in research began in AP Psychology class. Thank you to Ms. Maria Vita for being my first research mentor and with whom I published my first research paper, a replication of Solomon Asch's conformity study, in the *Walt Whitman High School Psychology Journal*. Thank you also to my undergraduate mentor, Dr. Irene Frieze. When I got bored in class, she encouraged me to continue in the sciences (instead of double majoring in English Literature and English Writing). She thought I had a future as a researcher. I would also like to acknowledge the team in Dr. Saul Shiffman's Smoking Research Group where I got my start in randomized controlled trials as well as my colleagues in the Texas Department of State Health Services Immunization Unit where I first worked as a professional epidemiologist. With the public health background I gained by working, I was ready to pursue a PhD.

Thank you to my committee members for their guidance throughout my PhD journey. I have benefited from their thoughtful research recommendations and professional advice. Thanks also to my coauthors, professors, and classmates from whom I also learned immensely.

Thank you to my parents who provided a loving and stable home in which to grow up. Thank you to my Poppop from whom I get my good looks and smarts. Thank you to my aunts and uncle in Pittsburgh for making sure that I was not starving in Oakland throughout my many years as a student. Thank you to my buddy, Saki, for getting me into long distance running even though he does not care much for it. It has been my escape. Thank you to the rest of my family for grounding me and providing ample examples of serving the community. Research is my way of doing so. Thank you to my friends for the necessary breaks from work.

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1.0 Background

1.1 The State of Diet in the United States

Major organizations like the American Cancer Society (ACS), specifically recommend healthful dietary patterns as the focus for health behavior change.[1] The American Heart Association (AHA) has similarly recommended healthful dietary patterns for improving cardiovascular health,[2] and the American Diabetes Association (ADA) has emphasized that various healthful eating patterns may be followed in the medical nutrition therapy provided to patients with diabetes and prediabetes.[3]

The US Department of Agriculture (USDA) and Department of Health and Human Services (HHS) are jointly responsible for defining what constitutes a healthy diet. Healthy diet is operationalized as the adequate intake of foods providing required vitamins and minerals and the moderate intake of foods with limited nutritional value. USDA and HHS jointly publish updated Dietary Guidelines for Americans (DGA) every 5 years (most currently 2020-2025) as the guidelines are required by statute to be based on the most current scientific and medical knowledge on what to eat and drink to promote health, reduce risk of disease, and meet nutrient needs. The stated goal of the DGA is to "make recommendations about the components of a healthy and nutritionally adequate diet to help promote health and prevent chronic disease" in the US population.[4]

Based on DGA standards Americans fail to meet recommendations for adequacy and moderation components of the diet. Seventy-five percent of Americans have dietary patterns low in fruits, vegetables, and dairy, 63% exceed added sugar limits, and 77% exceed saturated fat limits.[4] Although more than 50% meet or exceed total grain and protein recommendations, subgroup recommendations for these broad categories (e.g., whole grains and refined grains) are not being met. Across age and sex groups, the U.S. population largely fails to adhere to nutritional guidance.[4] Among young adults (19-20 years), 97% of males and 84% of females exceed sodium intake limits. This is similar among males and females 31-59 years (97% and 82%, respectively) and ≥60 years (94% and 72%, respectively).[4] All this may mean poor eating habits are transmitted to the next generation as children do not see good eating habits modelled and likely are not then given knowledge of cooking techniques and recipes for healthy foods.

Based on the most prevalent deficiencies in the US population, Healthy People 2030 includes nutrition and weight status goals for increasing consumption of fruits, vegetables (and specifically dark green vegetables, red and orange vegetables, and beans and peas), and whole grains (NWS-06 to NWS-09), decreasing consumption of added sugars, saturated fat, and sodium (NWS-10 to NSW-12), and increasing calcium, potassium, and vitamin D consumption (NWS-13 to NWS-15).[5]

Despite regularly updated dietary guidelines and goals for nutritional improvement reaching back to Healthy People 2000 and continuing to Healthy People 2030,[6-8] in general, the diet of most Americans is not adequate and has not improved much, if at all, over time. On some measures, dietary intake has actually worsened. For example, the percentage of US adults eating any fruit on a given day has decreased from 77.2% in 1999-2000 to only 64.9% according to data from the 2015-2018 National Health and Nutrition Examination Survey (NHANES).[9] As such, current efforts may need to be supplemented in order to achieve dietary improvements in the population.

1.2 Assessing Diet Wholistically

The numerous areas of diet in need of improvement suggest that intervening on the consumption of a single nutrient/food/food group may not be optimal or sufficient for improving health. Moreover, it is important to recognize that nutrients are not consumed in isolation.

An alternate research approach to focusing on single nutrients/foods/food groups is to examine dietary patterns, which combine nutrients/foods/food groups into a single meaningful cluster. If the dietary pattern effectively pools dietary elements necessary for health then by employing this holistic dietary measure in analyses one can account for more dietary elements while reducing the need to consider correlations and interactions between specific nutrients.[10] Additionally, because there are interactive and cumulative effects of various dietary components, a dietary pattern may be more related to a health outcome than any single component.

There are multiple methods for determining dietary patterns with no true gold standard. An appropriate method for defining dietary patterns should be driven by the research question.[11] One approach to assessing diet holistically is by conducting pattern analysis (e.g., factor analysis, cluster analysis, reduced rank regression,[10, 12] and classification and regression tree analysis[13]) using data collected on the consumption of individual nutrients/foods/food groups as described in detail elsewhere. These data-driven approaches are best used to answer questions about which dietary components are most related to health markers/outcomes and for questions seeking to explain variation in diets.[13] For example, a cluster analysis may reveal in the sample under study that three types groups of participants who are categorized as having: 1) high intake of meats and potatoes, 2) no intake of meat and high intake of vegetables, and 3) high intake of seafood and moderate meat and vegetable intake. A factor analysis would group dietary variables themselves into patterns with participants being ranked as to how closely their intake aligns with a specific pattern.

Another approach involves the use of a priori defined indices constructed based on the literature relating diet to health outcomes. These methods are appropriate when the research question relates to meeting dietary recommendations or when identifying if individuals following a particular diet (e.g., a Mediterranean diet) have a different risk profile than others.[13] As this dissertation is mainly concerned with questions related to meeting recommendations, a priori defined indices are the focus in the rest of this section.

1.2.1 Considerations for the Construction of a Priori Defined Indices

An a priori defined index creates a single numeric score that represents how adherent an individual is to the pattern of eating under consideration. Indices are meant to be multidimensional with the single numeric score calculated as the sum of scores generated from the subcomponents of the index. For example, a 10-item index may result in a total score ranging from 0-100 based on the summation of 0-10 scores for each subcomponent. Often this total score, not scores on subcomponents, are entered into analyses. This is because a score on a vegetable component that ranges from 0-10 does not represent a dietary pattern and thus does not offer a benefit over simply entering absolute vegetable intake into an analysis. However, when the score for the vegetable component is summed with the score on other components, the resultant total score does represent a pattern of eating.

According to Waijers, et. al.[14] there are several considerations for the construction of a diet quality index including the choice of components of the score (i.e., nutrients/foods/food groups) and how foods are assigned to food groups. For example, one index may choose to include sodium consumption as a component of the index while another may not. Whether pickles, ketchup, and French fries count as vegetables may seem trivial at first but does have implications for the construction of an index.

The choice of cut-off values for assigning scores, whether and how to adjust for energy intake, and the relative contribution of individual components to the total score are difficult but necessary considerations. For example, energy intake is important to consider as it is positively correlated with the intake of almost all nutrients, and energy intake itself is related to body size, physical activity, and metabolic efficiency. People with a larger body size consume more food and therefore more calories in general, making them more likely to achieve recommended levels of nutrient intake.[15] Total energy intake is correlated even with nutrients such as vitamins which do not contribute to energy intake, therefore, adjustment for energy is often important in epidemiological research, even if not considered in the index itself.[15] Whether an index is density-based (i.e., accounts for energy) or not, cut points must be determined. These cut points may be based off the consensus of experts or daily recommended allowances. Other times, quintiles of intake in a large, preferably representative sample, are used for the construction of the score. Additional considerations such as truncation might also be considered.[16]

1.2.2 Comparison of a Priori Defined Indices

As there is no gold standard for the method used to define a dietary pattern, similarly, there is no single dietary index that is the gold standard. The choice of a priori defined index will depend on multiple factors. For example, an index based on US dietary guidelines may not be appropriate for describing the dietary pattern of a Chinese population. A dietary index such as the Dietary Approaches to Stop Hypertension (DASH) diet may be better suited for studies assessing a relationship with blood pressure, as this was its original purpose. Indices with a larger range in possible scores may be more sensitive to change and thus useful in intervention studies. As a poor choice could lead to the observation of a null result because the index does not contain elements likely to be related to the health outcome, careful consideration should be given to choosing an index.

As a result of the need for outcome and population specific diet quality indices as well as an evolving understanding of the relationship between dietary constituents and disease, there are many different a priori defined indices used in research, including the Healthy Eating Index (HEI), the Alternate Healthy Eating Index (AHEI), the Diet Quality Index (DQI), indices based on the Mediterranean diet (e.g., Mediterranean Diet Score [MDS]) and DASH diet, as well as measures of dietary variety[17] and dietary indices that include weight and physical activity components (e.g., Mediterranean Lifestyle Index [MEDLIFE]).[18] Many of these indices have been further adapted for specific cultures (e.g., the Canadian HEI-C[19] and Brazilian BHEI[20]) and age groups (e.g., youth YHEI[21]) besides being regularly updated (e.g., HEI-1995,[22] 2005,[23] 2010,[24] 2015[25]).

There are some notable differences between indices including in the treatment of dairy intake. For example, the HEI views dairy intake positively while in the MDS, dairy consumption should be limited. The DQI and its versions do not score dairy products; however, calcium and intake is considered.[14]

One review which looked at 31 different indices found a range in component items from four for the Nordic Food Index to 45 in the Dietary Inflammatory Index.[26] The review also found that some indices have been used much more in research than others with versions of the MDS being used to investigate cardiovascular outcomes in 25 studies. Eighteen studies used some form of the DASH diet, 10 used the HEI, and 10 used the DQI. All other indices were used in ≤5 studies.[26]

As will become evident later in this introduction, sometimes a relationship with a risk factor or disease is found for certain indices but not others. Table 1 compares how select indices have been constructed. Detailed reviews of available diet quality indices have been published.[14, 26-29]

Table 1: Comparison of Select Diet Quality Indices

Index	Score Range	Number of Components	Basis of Score Assignment	Density-based
HEI-1995[22]	0-100	10	Cut points	-
HEI-2005[23]	0-100	12	Cut points	✓
HEI-2010[24]	0-100	12	Cut points	✓
HEI-2015[25]	0-100	13	Cut points	✓
DASH[30]	8-40	8	Quintiles	-
DASH-like[31]	0-8	8	Split at median	-
DQI-R[32]	0-100	10	Cut points	-
DQI-I[33]	0-100	5	Cut points	-
MDS[34]	0-9	9	Split at sex-specific median	-
aMed[35]	0-9	9	Split at median	-
Notes: aMed=Alternate Mediterranean Diet score; HEI=Healthy Eating Index; DASH=Dietary Approaches to Stop Hypertension; DQI-R=Diet Quality Index Revised; DQI-I=Diet Quality Index International; MDS=Mediterranean Diet Score				

Overall, while there are differences in components emphasized and scoring across diet quality indices, many diet quality indices are able to define a dietary pattern that is considered healthful making them appropriate for use in assessing diet quality-disease relationships and describing population-level eating patterns. For some indices at least, there is good agreement on the importance of intake of certain nutrients/foods/food groups.

For example, the HEI, AHEI, Alternate Mediterranean Diet Score (aMed), and DASH all consider whole grains, vegetables, fruit, and plant-based protein.[29] These four indices have been examined in considerable detail in the Dietary Patterns Methods project (DPMP). The DPMP draws data from three cohort studies (i.e., NIH-AARP Diet and Health Study, Multiethnic Cohort, and Women's Health Initiative Observational Study) all of which calculate diet quality using the four indices. The four indices relate well to each other. For example, correlations between HEI and the DASH ranged from 0.62 to 0.69 in women and 0.69 to 0.72 in men across cohorts. The various indices also classify individuals consistently into identical or adjacent quintiles, with consistency across cohorts and indices ranging from 69–84%.[29] In addition, these indices also relate to all-cause, cardiovascular (CVD), and cancer mortality in a similar way. Within each cohort, the hazard ratio (HR) is fairly similar across indices used. Also, between cohorts, the HRs are fairly similar.[29]

1.3 The Healthy Eating Index (HEI)

Among existing a priori dietary indices, we will focus on the Healthy Eating Index (HEI), as it is a measure of diet quality aligned with the DGA and it is used in the research conducted as part of this dissertation.[25] Originally developed in 1995,[22] a new version of the HEI is published to match each new version of the DGA, usually about three years after DGA publication. As the index aligns with the DGA, it can be applied to those 2 years of age or older whom the DGA targets.

While all versions of the HEI measure diet quality, defined based on the guidelines in effect at the time, comparison of scores across versions must be done carefully. The biggest difference is between the 1995 version, which did not score on a density basis, and all subsequent versions, which did. Thus, the interpretation of an association between the 1995 version and disease will be different from the interpretation of the association with disease for other versions. Changes in scoring standards (e.g., HEI-2015 splits into two components the 'empty calories' component of HEI-2005 and 2010) also need to be considered. Indeed, differences in scoring of versions has been demonstrated with HEI-2010 scores about 6 points lower than HEI-2005 scores when calculated using the same NHANES data.[36]

The HEI has demonstrated construct validity, reliability, and criterion validity.[37, 38] This multidimensional score has low to moderate correlations between components (0.01 to 0.49), exhibits sufficient variation in the population (mean=56.6; 1st percentile=32.6; 99th percentile: 81.2), and differentiates between subgroups of the population known to have different eating patterns (e.g., the mean score of 53.3 among individuals who smoke was significantly [p<0.01] less than the score of 59.7 among those who do not).[37] The correlation between HEI diet quality and diet quantity is low (<0.25 for all components), suggesting a desirable independence between measures.[37]

As shown in Table 2, the most current version, HEI-2015, assigns a different number of maximum points to each food group or nutrient based on the proportion of intake.[25] This is as a proportion of calories for most components except 1) fatty acids, which is scored as the ratio of unsaturated fatty acids to saturated fatty acids, and 2) added sugars and saturated fats, which are scored based on percent of energy intake. Intakes between the minimum and maximum standard are scored proportionally. There are 9 components (e.g., whole grains) for which a maximum score requires an adequate intake of that component. Four components must be eaten in moderation in order to achieve the maximum score (e.g., sodium). Scores for each of the 13 components of the HEI are summed to generate a total score from 0 to 100. The optimal HEI diet score is 100, but a score of 74 would satisfy Healthy People 2020 objectives.[39]

Table 2: Components and Scoring of the Healthy Eating Index-2015

Adequacy Components	Standard for Min Score of 0	Standard for Max Score	Max Score
Total Fruits	No fruit	≥0.8 c /1,000 kcal	5
Whole Fruits	No whole fruit	≥0.4 c /1,000 kcal	5
Total Vegetables	No vegetables	≥1.1 c /1,000 kcal	5
Greens and Beans	No dark green vegetables or beans and peas	≥0.2 c /1,000 kcal	5
Whole Grains	No whole grains	≥1.5 oz /1,000 kcal	10
Dairy	No dairy	≥1.3 c /1,000 kcal	10
Total Protein Foods	No protein foods	≥2.5 oz /1,000 kcal	5
Seafood and Plant Proteins	No seafood or plant proteins	≥0.8 c /1,000 kcal	5
Fatty Acids	(PUFA+MUFA)/SFA ≤1.2	(PUFA+MUFA)/SFA ≥2.5	10
Moderation Components	**Standard for Min Score**	**Standard for Max Score**	**Max Score**
Refined Grains	≥4.3 oz /1,000 kcal	≤1.8 oz /1,000 kcal	10
Sodium	≥2.0 g /1,000 kcal	≤1.1 g /1,000 kcal	10
Added Sugars	≥26% of energy	≤6.5% of energy	10
Saturated Fats	≥16% of energy	≤8% of energy	10
		Total Points	100
Notes: c=cup, g=grams, kcal=kilocalories, oz=ounces, PUFA=polyunsaturated fatty acid, MUFA= monounsaturated fatty acid, SFA=saturated fatty acid			

The HEI has been applied to epidemiology and intervention research with purpose-specific recommendations for the analysis and interpretation of scores.[36] Although it is unclear what a clinically significant improvement in HEI score is, a meaningful difference between groups may be five to six points among adults although the distribution of scores (standard deviation=10-12 points) in the population under study might change what differences are considered important.[36] As overall diet quality is the focus of the index, the total HEI score is of most interest to researchers. However, in addition to using the total HEI score as a continuous variable, examination of the components of the HEI total score visually is recommended to allow insight into the dietary pattern as multiple dietary patterns may result in the same total score (Figure 1).[36] In the radar plots below, the best possible score would be represented by touching the outermost ring for all components.

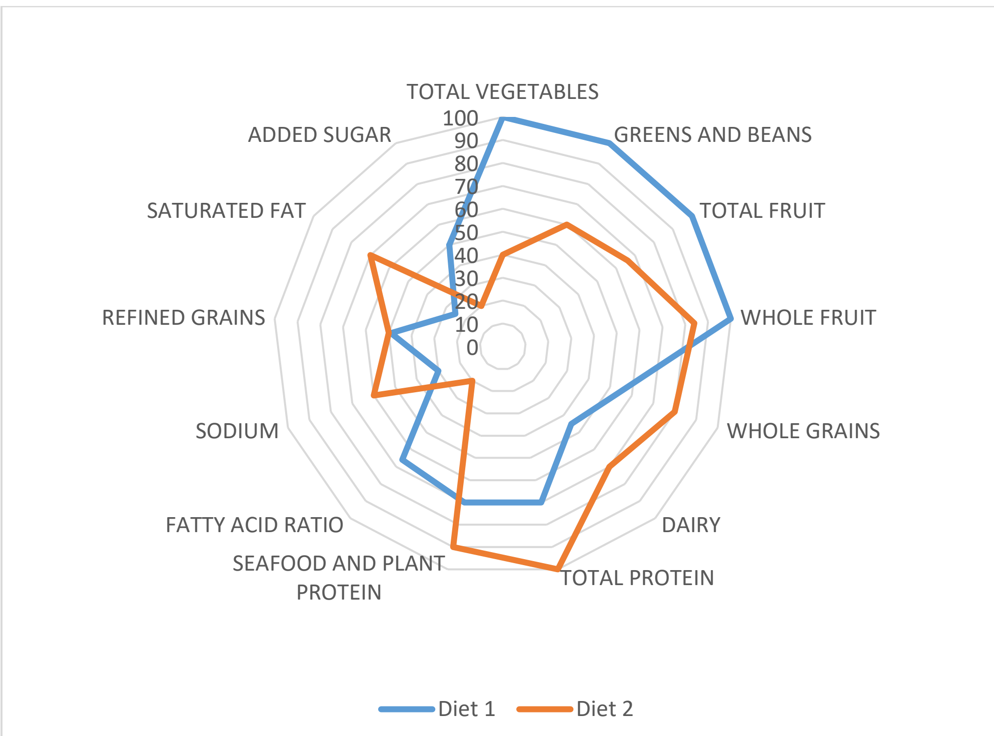


Figure 1: Different Dietary Patterns with the Same Total HEI Score of 59

Figure 2 shows HEI-2015 scores for the US population by age group. As can be seen in the figure, the population does well with whole fruit, seafood and plant protein, and total protein components of the HEI, with adults ≥65 years maximizing their scores for these components.

However, other components, particularly the moderation components have the most room for improvement in the population.

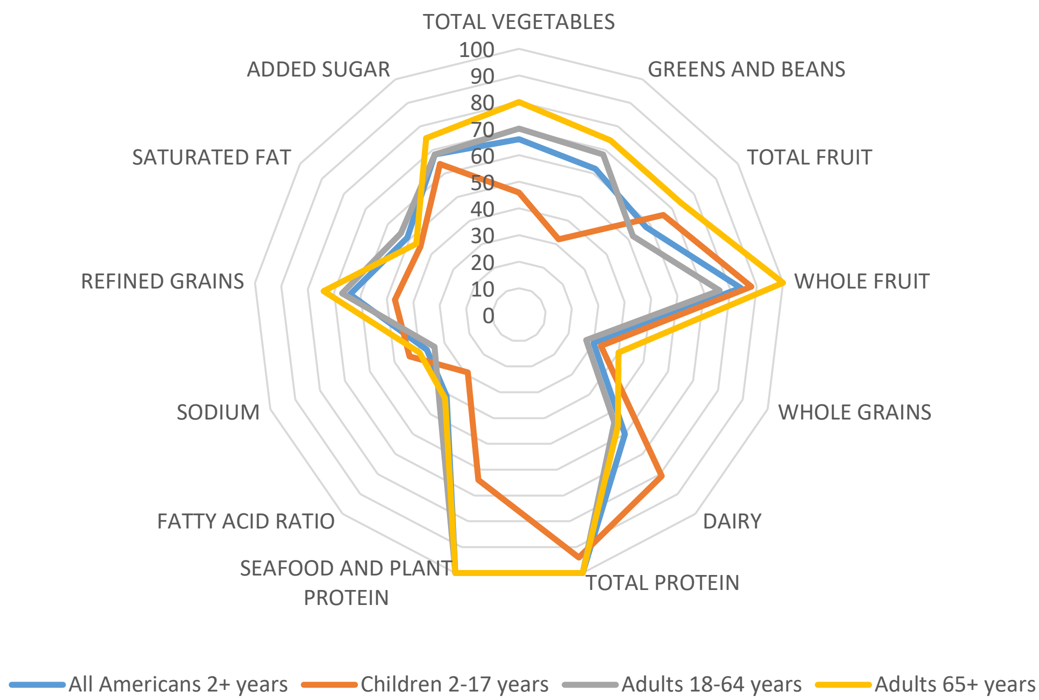


Figure 2: HEI-2015 Component Score by Age Group

With the average HEI-2015 score only 59 out of 100 possible points and little evidence of improvement over the years (score of 56 in 2005-2006),[40] it is clear the overall dietary pattern needs to be improved. While higher scores are observed among pregnant and lactating women (63 and 62, respectively) compared to 54 among peers, diet quality is still less than desirable.[40] Again, while there are differences among age groups, with HEI scores declining through childhood and adolescence (51 points among those 14-18 years) then increasing, even among older adults, average HEI scores are only 63 points (Figure 3).[40] Strikingly, the pattern of eating of children is broadly similar to that of adults likely because the dietary intake of children is largely controlled by their guardians and because children may adopt eating habits that they see modelled by adults. While there may be differences in diet quality based on smoking status,[37] race and ethnicity, income, and education,[41] with evidence of interactions between race and socio-economic status,[42] there is no subgroup that could not benefit from improvements in diet quality.

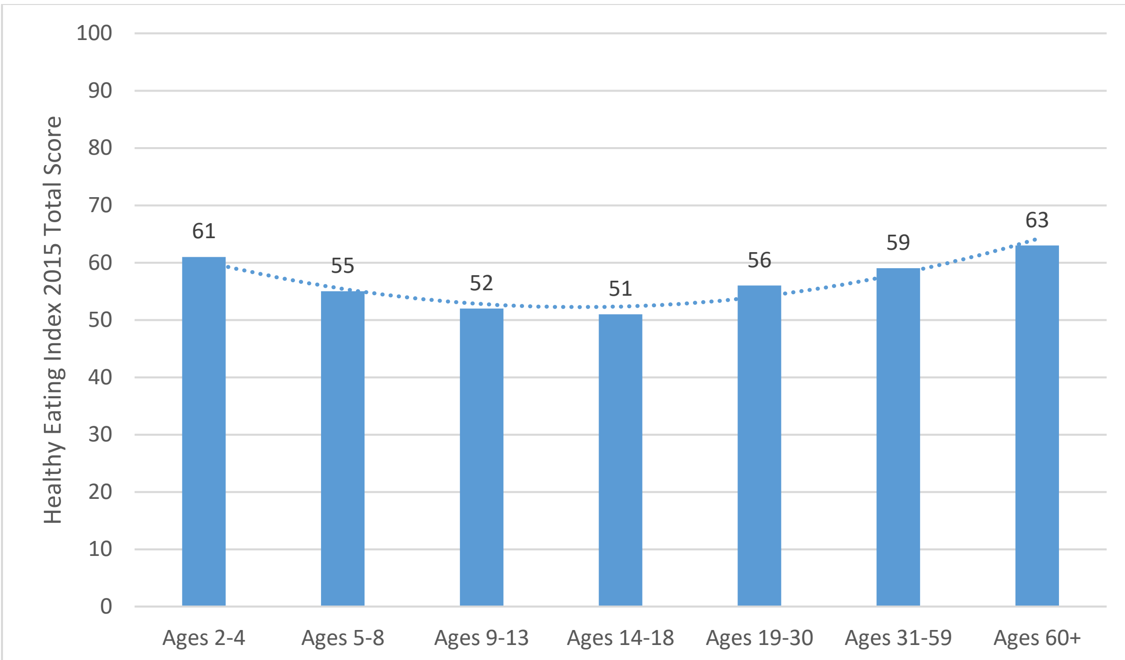


Figure 3: Avergae Healthy Eating Index-2015 Total Score by Age Group

1.4 Biological Mechanisms through which Diet Affects Health

In a meeting of experts brought together by the National Cancer Institute (NCI) and National Institutes of Health (NIH) Office of Disease Prevention (ODS), one issue noted with diet quality indices is that the ability to explain etiology is hampered by the multidimensional nature of the index. Trying to understand the biological pathway between diet quality and disease through comparison of indices with and without specific components has been suggested; however, such indirect evidence can be difficult to parse.[43]

While the biological link between a multidimensional score can be difficult to understand given that it likely involves multiple pathways, HEI and other diet quality scores have been shown to relate to biomarker concentrations (i.e., α-carotene, β-carotene, β-cryptoxanthin, lutein, vitamin C,[44] folate, and vitamin E[45]) and serum metabolites (i.e., *N*-methylproline, glycerate, pyridoxate, threodoxate, deoxycarnitine, and stachydrine).[46] Diet quality indices also have been found to relate to inflammatory markers (e.g., C-reactive protein [CRP], interleukin 6 [IL-6], and adiponectin) in cross-sectional analyses with less consistent results longitudinally.[47] Additionally, a systematic review of cohort and intervention studies found that healthful dietary patterns inversely relate to oxidative stress markers (e.g., Fluorescent oxidation product [FlOP]), but note that most studies were deemed low/moderate quality.[48] Some more recent work has shown possible links between diet quality and DNA methylation at cytosine-phosphate-guanine (CPG) sites[49] as well as effects on the microbiome.[50]

Besides these relationships, diet in general is believed to be related to the risk of coronary heart disease (CHD) through multiple biological mechanisms such as lipid levels, blood pressure, thrombotic tendency, cardiac rhythm, endothelial function, hyperglycemia/hyperinsulinemia, and homocysteine levels.[51] Potential pathways through which diet quality might affect adiposity, include through energy intake/expenditure, the microbiome, body fat composition, and metabolic function.[52]

As indices are better suited for prediction than for etiology, this section will discuss what is generally known about the biological mechanisms by which specific dietary constituents, instead of diet quality holistically, affect weight status and health.[53] In particular, we will focus briefly on components of the HEI-2015; however, for even more specifics about how micronutrients might affect health (e.g., Vitamin A and lung cancer[54]) other sources may be consulted.

1.4.1 Fruits, Vegetables, and Whole Grains

Fruits and vegetables are rich in vitamins and minerals which have many important roles in the body such as Vitamin C (e.g., antioxidant, important for metabolism), folic acid (e.g., red blood cell maturation, amino acid metabolism), provitamin a (e.g., skin and mucus membranes, reproduction, immune function), calcium (e.g., bone formation, blood clotting, muscle contraction and relaxation, nerve transmission), potassium (e.g., acid-base balance, blood pressure regulation), and manganese (e.g., energy metabolism, lipoprotein clearance, and synthesis of fatty acids).[55, 56] Similarly, whole grains are a source of dietary fiber along with vitamins, minerals, and healthy fats.

The energy density of foods is considered in many weight loss programs' recommendations. Popularly referred to as 'volumetrics', an energy density approach to eating benefits weight loss through earlier termination of eating events, prolonging time between eating events, and reduction of intake.[57, 58] Fruits and vegetables contribute a lower number of calories per unit weight compared to other foods because of their relatively high fiber and water content.

In the PREMIER trial, energy density reduction (increasing the weight of food but decreasing the energy intake) was associated with weight loss across treatment groups.[59] In the Preventing Overweight Using Novel Dietary Strategies (POUNDS Lost) study, participants were assigned to one of four dietary intervention groups with high vs. low fat and high vs. average protein prescriptions. Fiber intake, to be attained through grain, food, vegetable, nut, and seed consumption, was associated with weight loss controlling for energy intake, dietary adherence, and other macronutrient intake.[60] In another trial comparing a reduced fat diet (RF) to a reduced fat plus increased fruit and vegetable diet (RD+FV), while weight loss results were fairly similar between groups, the RF+FV groups have lower energy density and reported less hunger.[61] Higher fruit and vegetable consumption, particularly of green leafy vegetables and vitamin C-rich fruits and vegetables, has been associated with reduced risk of coronary heart disease adjusted for cardiovascular risk factors in the Nurses' Health and Health Professionals' Follow-Up studies.[62]

The fiber found in fruits, vegetables, and whole grains may slow the absorption of carbohydrates which in turn results in less of a spike in blood glucose levels.[63] This is important as postprandial glucose levels have been shown to relate to cardiovascular risk even among non-glucose intolerant patients.[64, 65] In the Nurses' Health Study II, higher glycemic index was associated with increased risk of developing diabetes while cereal fiber intake was inversely associated controlling for BMI, family history of diabetes, and other confounders.[66]

1.4.2 Dairy

While there is generally little disagreement between experts on the importance of fruit, vegetable, and whole grain consumption, the biological mechanisms through which dairy products affect health may be dependent on the type of product under study and thus the treatment of dairy by diet quality indices may differ.[52] For example, probiotic properties of yogurt may be protective against obesity (body mass index [BMI]$\geq$30 kg/m^2).[67] Fermentation may be partly responsible for lower risk of diabetes seen with cheese and fermented milk but not regular milk, explained by the synthesis of vitamin K2, which may improve insulin sensitivity.[68, 69] Dairy products may contribute to excess caloric intake due to relatively high fat content and added sugar in flavored yogurt and ice cream thus affecting weight status. However, the concern with caloric intake may be slightly overblown. In an analysis combining data from the Nurses' Health Study, Nurses' Health Study II, and Health Professionals Follow-Up Study, while consumption of regular cheese was positively associated with weight gain, milk consumption was not associated with weight gain. Yogurt and low-fat cheese consumption were negatively associated with weight gain.[70]

Dairy recommendations may be driven in part by the calcium and vitamin D content of these products.[52] Sufficient Vitamin D and calcium is important for the prevention of rickets in children and osteoporosis in older adults.[71, 72] About ¾ of calcium intake in US comes from calcium-rich dairy sources with additional intake coming from other sources such as fortified grains;[73] those that avoid dairy intake are at risk for a calcium deficiency.[72] Unlike calcium, Vitamin D naturally occurs in few foods; therefore, fortified foods account for most of the US dietary Vitamin D intake.[74] Interestingly, while cow and plant-based milks are Vitamin D fortified in the US,[75] many other dairy products are not. While obesity does not affect the ability to absorb Vitamin D,[76] those with obesity are at increased risk of deficiency as excess subcutaneous fat sequesters more Vitamin D than in normal weight individuals.[73] Vitamin D supplementation and/or high dietary intake do not clearly offer a weight loss benefit[77] with similar results seen for calcium.[78]

1.4.3 Protein

There are many roles of protein in the body. For example, protein is used to make up bone tissue, tendons, ligaments, cartilage, skin, and muscle, but also functions as enzymes that are necessary for various chemical reactions in the body. As evidencing the connected nature of dietary consumption, protein intake is linked with fatty acid intake. Protein consumption is a major source of fatty acids and vitamin B12, for example, which are important for tissue strength, cholesterol metabolism, muscle tone, heme development, blood clothing, and heart action.[55, 79, 80]

Protein deficiency in the diet may be linked to micronutrient deficiencies in folate, iodine, and iron. Too little protein in the diet, although rare, can lead to death. On the other hand, it is hypothesized that high protein diets may relate to osteoporosis through a blocking of calcium absorption although this is still unclear. Another mechanism through which high protein diets may affect health is indirect. Through competition, high protein diets may prevent the consumption of other foods that contain important vitamins and minerals.[81]

Sufficient protein intake is important in several populations. For example, in weight loss interventions among older adults where physical function and sarcopenia are concerns, recommendations for sufficient protein intake in diet and/or supplements are integral.[82] Meat and seafood are the richest sources of iron in the diet with about half of iron intake coming from fortified grain products in the US.[83] Specific groups are at risk for iron deficiency. As such, HP2030 has goals for decreasing iron deficiency in children 1-2 years and girls and women 12-49 years.[5] Iron deficiency can progress to anemia and may have negative health effects ranging from fatigue and gastrointestinal symptoms in adults to cognitive abnormalities in children to hospitalization and mortality among patients with heart failure.[83, 84]

1.4.4 Fatty Acids

Monounsaturated and polyunsaturated fatty acids are important for cell development and healthy skin. Essential fatty acids (omega-3 and -6), found in fish, flaxseed oil, and leafy greens, help to regulate blood pressure and affect immune system function. Consumption of polyunsaturated fatty acids lowers low-density lipoprotein cholesterol (LDL-C) as opposed to saturated fatty acids which increase LDL-C.[85] Specific recommendations for the consumption of long-chain n-3 polyunsaturated fatty acids from seafood have been published by the American Heart Association as evidence suggests a potential risk reduction for cardiovascular disease with hypothesized antiarrhythmic, anti-inflammatory, hematologic, and endothelial mechanism.[86] Similar evidence of a potential cardioprotective and hypoglycemic effect of monosaturated fatty acids exist although there is some ambiguity still remaining in the evidence base for the recommendation of MUFAs as a therapeutic target.[87] Saturated fatty acids are found mostly in animal products, which is why dietary guidelines emphasize the importance of consumption of seafood and plant protein which have unsaturated fatty acids.[85]

The classical model by which fat intake affects CVD risk posits higher levels of saturated fat and cholesterol, along with lower levels of polyunsaturated fat, lead to increased serum cholesterol. This in turns leads to plaque formation, coronary artery narrowing, and myocardial infarction. While evidence supporting this hypothesis is somewhat mixed, the relationship between LDL-C and triglycerides and CVD risk is clear.[88]

Notably, more recent mendelian randomization analyses have suggested no causal relationship between high-density lipoprotein cholesterol (HDL-C) and cardiovascular risk likely because HDL-C does not reflect function. Raising HDL-C levels has not resulted in therapeutic benefit although targeting metrics of HDL function might still be useful. Similar research has called into question the cardiac protection of high HDL-C levels as high HDL-C genetic etiologies have not been associated with reduced risk of heart attack and in some cases, genes are related to greater risk of heart attack.[89, 90]

1.4.5 Sodium

Many diet quality indices focus on food groups, with sodium being one of the micronutrients that is usually considered of importance, especially in indices such as HEI and DASH as it is well accepted that high sodium intake increases blood pressure. Sodium is influenced by the renin-angiotensin aldosterone system and the sympathetic nervous system which regulate renal and medullary blood flow thus affecting blood pressure. Because of increased blood pressure related to high sodium intake, increased left ventricular mass may result from the additional stress on the heart. However, sodium may also affect the heart independent of this effect on blood pressure.[91] There are several important additional roles of sodium including maintaining fluid balance, transmitting nerve impulses, and the absorption of nutrients.[92]

1.4.6 Sugar

Much policy focus has been devoted to decreasing the consumption of sugar-sweetened beverages[93] as it is the largest contributor to added sugars in the US diet and has been linked to weight gain in children and adults.[94] However, there are many other contributors to added sugar including desserts and sweet snacks as well as candy.[40] As opposed to naturally occurring sugars in fruits, for example, these sources of added sugar may not contribute any or many vitamins or minerals which make them a clear target for intervention.

While certainly not the only contributor, sugar intake contributes significantly to weight gain through the large number of calories ingested. One consequence of obesity is the development of Type 2 diabetes mellitus (T2D). Indeed, 86.4% of men and 84.6% of women with T2D also have overweight or obesity. In addition to BMI, waist circumference is also associated with T2D.

Those with normal glucose levels have smaller waist circumference than those with prediabetes and diabetes.[95]

Briefly, the progression to T2D is as such: insulin-dependent tissues do not respond normally to the presence of insulin by taking up glucose.[96] Because of this, blood glucose levels are higher than normal. Programmed cellular death then begins to occur in the islet beta cells which produce insulin. This apoptosis is triggered by the beta cells' continued attempts to deal with high levels of glucose by secreting ever-increasing amounts of insulin. When beta cells die, then less insulin is produced which further prevents glucose uptake by insulin-dependent cells.[97]

1.5 Traditional Dietary Assessment Methods

Having established that diet plays a biologically plausible role in disease etiology, in order to conduct and parse results of dietary research, the complexities of measuring diet must be considered. There is no gold-standard for dietary assessment. The choice of method will depend on many factors including the research question, dietary component(s) of interest, time, and cost.[98-100] Although criticism of dietary data has been voiced and may be based on documented difficulties collecting and analyzing such data, self-reported dietary data may still be used in research and policy development.[101] This review will focus on the advantages and disadvantages of the traditional self-report instruments as these methods lend themselves to the subsequent calculation of diet quality indices; however, we briefly review other methods of dietary data collection.

Collection of biomarker data requires the careful consideration of homeostatic mechanisms, bioavailability, repeat measures, timing of collection, and storage among other considerations.[102] Because biomarkers are not available for all micro- and macro-nutrients of interest, they may be used only in certain situations. Some examples of biomarkers used in nutritional epidemiology include doubly labelled water for energy estimation and urinary excretions for sodium, potassium, and protein intake estimation.[102] Additional methods include direct observation, which is too intensive to be viable except in specific study settings. In clinical practice, dietary screeners may be preferred as quick assessment and educational tools. The NCI maintains the Register of Validated Short Dietary Assessment Instruments[103] with a dedicated webpage listing over 135 dietary screeners with associated validation studies.

1.5.1 Food Frequency Questionnaire (FFQ)

Food frequency questionnaires (FFQ) are used in many large epidemiological studies because of their ease of administration and lower cost compared to dietary recalls. As usual dietary intake, not short-term dietary intake, is usually of interest, an advantage of a FFQ is that it is a global assessment of diet. FFQs can be used qualitatively, but as they are semi-quantitative, they can be compared to dietary recall and record methods. These self-administered questionnaires range in their length. FFQs such as the Women's Health Initiative (WHI) FFQ and Block FFQ are commonly used and adapted. FFQs are often validated against biomarker concentrations and other self-report measures of diet.[104] The items available on FFQs are often tailored to the population of interest, which may be particularly important when working with participants who have different cultural eating habits than the general US population. The ability to write-in items may also be important and careful consideration needs to be paid to the ordering of items. Review of responses by dietitians may be helpful. Much work has been done in consideration of missingness in FFQs.[10, 105] Despite its numerous advantages, FFQs is subject to more systematic bias than dietary records or recalls.[104] It is subject to both recall bias and social desirability bias. Table 3 provides a comparison between the traditional self-report measures.

1.5.2 Dietary Record (DR)

Dietary records (DR) or food records involve participants' recording in real-time their consumption of foods thereby eliminating recall bias. Reactivity is the main concern with dietary records whereby participants may alter their eating in order to lessen the burden of recording (e.g., eat fewer foods and/or foods that are easier to describe), because of social desirability. This can be a major issue when trying to assess dietary change as the change seen using this method may simply represent a transitory, not real, change to the eating pattern.

However, such reactivity may help reinforce desired change when diet is an intervention target.[106] Indeed, this "self-monitoring" is often recommended to those seeking to lose weight, but as a means of measuring change in an intervention, it is not desirable. There is too much of a risk of differential response bias with the intervention arm reporting diet differently than the control arm.

With sufficient training, participants perform well in recording their diet; however, it is often necessary for dietitians or other trained personnel to review incomplete dietary records and elicit additional information from participants. Both paper-and-pencil and digital (e.g., personal digital assistant [PDA], phone app, digital photography) dietary records have been made available in recent years.[107-110] While accuracy of photographic capture may be fairly good in laboratory settings, in free-living situations, the performance of this method is more variable although participant burden is judged to be less than other methods of recording.[110] DR collection methods are validated using biomarkers, 24-hour recalls, and direct observation.[106]

1.5.3 24-Hour Dietary Recall (24HR)

This method of unannounced 24-hour recalls (24-HR) requires that participants be queried on their eating behavior in the past 24 hours with no knowledge of when the assessment will take place. This method, unlike the FFQ, is quantitative in nature and unlike the record, it is not subject to reactivity. However, even this method is not without bias (e.g., social desirability bias). The short duration between the eating event and the recall limits recall bias; however, multi-pass methods are still useful as it is not uncommon for participants to forget to report certain items especially snacks, beverages, and condiments.[111] Multi-pass methods involve participants being prompted regarding frequently missed foods after having reported all foods eaten during the day. Usually a trained interviewer, preferably a dietitian, conducts the recall.

Issues in administration can take away the advantages of recalls. For example, when investigators allow participants knowledge of when recalls will occur or allow participants to self-select recall days, the advantage of recalls are diminished as reactivity again may need to be considered. There is also significant burden to researchers in deploying this method as the unannounced nature means that participants may not respond to a query, thus requiring multiple attempts to get a response on a random day. 24-HR can be validated using biomarkers and direct observation.[112]

While unannounced dietary recalls are often interviewer-administered, self-administered versions have been developed that mimic multi-pass methods. The Automated Self-Administered 24-hour recall (ASA-24) system created by the NCI uses multiple databases to pull nutrient, supplement, and food group information.[113] ASA-24 performs well compared to interviewer-administered recall and DRs[114] and better than FFQs.[115] There are relatively similar levels of misreporting across methods[116] with ASA-24 having similar reliability.[117-119] While usability issues with ASA-24 data have been documented in low-income adults,[120] the provision of aid does not substantially increase the accuracy of reporting.[121] The feasibility of its use in adults ≥50 years has been demonstrated with good response rates across genders and a decline in the amount of time it takes to complete recalls with each subsequent recall.[122] HEI scores calculated from ASA recalls were similar to scores calculated based on 4-day DRs and higher than those based on FFQs.[122]

Table 3: Comparison of Traditional Dietary Self-Report Instruments

	24HR	FR	FFQ
Suitability for Evaluating Interventions	Yes	No	Yes
Time Frame	Short term	Short term	Long term
Major Error Type	Random	Random	Systematic
Reactivity Potential	Low	High	Low
Time to Complete	>20 minutes	>20 minutes	>20 minutes
Memory Requirements	Specific	Not Applicable	Generic
Difficulty	Low	Low	High

1.5.4 Multiple Administrations

Diet is complex to measure because eating is a behavior that almost everyone engages in every day, multiple times a day. As such, it does not represent a discrete exposure. In addition, eating behaviors are quite variable naturally. For example, consecutive days of recall tend to be more correlated than non-consecutive days,[123] and weekday and weekend eating differ quite substantially.[124] There may also be seasonal variations in eating behaviors, especially in regards to availability of fruits and vegetables,[124] although this may be of slightly less concern in countries with a steady food supply. However, even in the US, eating behaviors may vary in a cyclic way. For example, while no seasonal variations in diet quality have been observed in midlife women in the US, diet quality was lower during the winter holiday season compared to the non-holiday winter season and the rest of the year.[125] Because of the natural variation in diet, assessment on a single day or even a few days may poorly represent usual dietary intake.

Thus, regardless of whether dietary records or recalls are chosen as the method of assessment, it is important to consider the capture of multiple days of intake as both these methods capture only short-term intake while researchers are more often interested in usual intake. Fewer recalls are needed to reasonably characterize energy consumption than are required for macronutrients and fewer days are needed to capture macronutrients than for micronutrients. For example, for 95% of observed values to lie within 40% of the true mean, 4 days of data may be sufficient for estimating total fat intake while 26 days would be needed for Vitamin A.[126] Similarly, fewer recalls may be necessary when attempting to estimate the mean intake for a group with more recalls needed for more complex estimation such as examining correlates of intake. Researchers must balance the added cost of training additional participants in dietary collection methods with the greater statistical efficiency of adding more participants compared to adding more recalls per participant.[123] Of note, despite capturing diet globally, multiple administrations of FFQs may be warranted in prospective analyses with long follow-up in order to account for long-term variations in diet.[127]

1.6 Measurement Error in Dietary Data

There are many points at which error can arise in dietary data collection including from the instrument used, as already discussed. Methods for reducing the various forms of error/controlling bias include the use of food models to aid participant estimation of intake, training of participants in the dietary collection method, and collection of data on potential confounders (e.g., physical activity). Specific considerations for the identification of outliers, consideration of nutrient databases, calibration of instruments, scoring of multidimensional indices, and other considerations are discussed.

1.6.1 Nutrient Databases

Error may occur through the underlying databases that are used to pull nutrient information.[98] First, foods consumed must be represented in the database being used. Regional and ethnic foods and dishes may need to be added to a database prior to conducting dietary analyses among special populations and/or databases maintained by other countries might be utilized.[128] Another consideration the stability of nutrients. Storage, preservation, and preparation methods may change the nutrient content of a given food item such that a database might consider providing information for the various preparations.[128] Nutrient information for a given food, may differ dependent on the place in which the food was grown and over time. For example, the selenium content of the soil has been shown to vary between and within countries thus affecting the amount of selenium available in a given food.[128] This variability makes estimation of intake and bioavailability in humans difficult and could be partially responsible for variations seen in study results among different populations and over time. Even if you were to assume nutrient stability other issues can occur with databases. When nutrient information is incorrect for a commonly consumed food, for example, systematic error will result but because the food is eaten with a different frequency by participants, the magnitude of this error will differ by person.[127]

1.6.2 Outlier Identification

Factors, such as higher BMI have been associated with greater underreporting of energy and protein intake.[129] Many previous research studies have used Goldberg cut-offs to identify under- and over-reporting of caloric intake specifically. Goldberg cut-offs define an individualized cut point for plausible energy consumption based on basal metabolic rate and physical activity level (as well as calculation and/or estimation of multiple coefficients of variation).[116] However, Goldberg cut-offs are meant for use in weight stable participants and all the data needed for estimation may not be available.

Other methods for outlier identification include pre-determined cut points such as those developed by Dr. Walter Willet and those based on the 5th and 95th percentile of intakes reported in NHANES (Table 4) as well as study-specific identification of outliers using traditional statistical methods. Outlier identification may be more important for some methods of collection than others. For 24-HR or DRs, which represent only a single day of intake, not usual intake, an extreme value for caloric intake, is not necessarily unexpected or incorrect as such extreme intake does occur. Therefore, removing outliers when using these methods, especially when the purpose of the analysis is to estimate the population level distribution of intake, may not be needed. Extremely high and low intakes will cancel out leaving a good estimate of the true mean, although the standard deviation will be exaggerated. Statistical methods for correcting standard deviations are available.[127]

There are benefits and limitations to each method of determining over- and under-reporting of energy intake such that it is recommended to conduct analyses without exclusion and then apply exclusion methods to determine if and how results might be sensitive to outliers.[10, 130]

While outlier identification for macro- and micro-nutrients may be of interest, most work has focused on outlier identification for energy.

Table 4: Gender-Specific kcal Cut Points for Energy Under- and Over-Reporting

	Sex	Willet	NHANES
Underreporting	Men	<800	<650
	Women	<500	<600
Overreporting	Men	>4000	>5700
	Women	>3500	>4400

1.6.3 Calibration Studies

As already mentioned, there is no true gold standard for the collection of dietary data. Therefore, when budgets allow, collecting dietary data using more than one method (e.g., biomarkers and dietary recalls) for at least a subsample can help reduce error as errors are assumed to be uncorrelated across methods. For example, the error inherent in the collection of biomarkers should not be related to the error that arises from the recall bias and semi-quantitative nature associated with a food frequency questionnaire. The dietary estimates from the FFQ can then be calibrated. This strategy may be useful to employ in large epidemiological studies.[101]

Using multiple methods of dietary assessment can also be used for regression calibration whereby the estimates of association between diet and disease are adjusted, not the estimates of intake from the instrument itself. One issue with both instrument calibration and regression calibration, however, is that researchers must still assume that one measure of diet is true or at least unbiased.

1.6.4 Healthy Eating Index Calculation from Traditional Self-Report Measures of Diet

Because of the multidimensional nature of indices, there are additional statistical issues with diet quality indices that go beyond what has already been discussed in regards to diet generally. For one, it can be difficult to deal with the correlations between each component and energy, all components and energy intake, and intakes and nutrient-nutrient interactions.[14]

For the HEI, there are five ways to calculate scores from dietary recalls and records: the simple scoring algorithm, mean ratio, and population ratio methods as well as the more computational intensive bivariate and multivariate methods.[36] The various methods of HEI calculation grew out of the NCI method of calculation[131] with the choice of calculation method dependent on the purpose of the study.[36] Newer methods attempt to account for correlations in addition to considering measurement error and accounting for episodic consumption. Table 5 summarizes the steps for calculation, analytical abilities, and research questions for which each method is suited.

Table 5: Description of Analytical Considerations for the Calculation of the Healthy Eating Index when Using Dietary Recalls

	Simple Scoring Algorithm	Mean Ratio	Population Ratio	Bivariate	Multivariate
Steps for Describing Dietary Intake	1. Derive Sums 2. Construct Ratios 3. Score 4. Calculate Means	1. Derive Sums 2. Construct Ratios 3. Calculate Means 4. Score	1. Derive Sums 2. Calculate Means 3. Construct Ratios 4. Score	1. Derive Sums 2. Model 3. Construct Ratios 4. Estimate 5. Score 6. Calculate Means	1. Separate 2. Model 3. Derive Sums 4. Construct Ratios 5. Estimate 6. Score 7. Calculate Means
Analytical Abilities					
Adjusts for Measurement Error	No	Using mean	Using mean	Yes, model	Yes, model
Considers Episodic Consumption	No	Yes, but ignores correlation between probability and amount	Yes, but ignores correlation between probability and amount	Yes	Yes
Considers Skewness	No	No	No	Yes	Yes
Accounts for Correlation between Each Constituent and Energy	Yes, individual	No	No	Yes	Yes
Accounts for Correlation between All Constituent and Energy	No	No	No	No	Yes
Use for Research					
Population Mean Intake	Possible	Possible	Recommended	-	-
Population Mean Intake and Distribution	-	-	-	Recommended (provides distribution of only component scores)	Recommended (provides distribution of total & component scores)

Regression Analyses	Recommended	-	-	Recommended	Recommended (methods under development)
Compare Intervention Groups	See methods for estimating mean and distribution of intake				
Describing Intake for an Individual (Clinical Use)	Recommended	-	-	-	-
Adapted from: Kirkpatrick, 2018[36] & https://epi.grants.cancer.gov/hei[132]					

Relevant to the aims of this dissertation, the population ratio method, bivariate method, and multivariate method are recommended for assessing the effect of an intervention. The bivariate[133, 134] and multivariate[135] methods require sufficiently large datasets[36] and ≥2 recalls on at least a subsample. This is because some foods like fruit juice are consumed episodically, meaning that they are not consumed every day by most people. As estimation of fruit juice consumption is necessary for the calculation of the total fruit component score, without a large enough dataset the occurrence of individuals with two or more days of non-zero fruit juice consumption will be small thus resulting in large standard errors. Indeed, in simulation studies, convergence issues arose when there were less than 50 people with such intake.[136] When use of the bivariate or multivariate methods are not viable, the population ratio method must be used instead.

The population ratio method is less biased than the simple scoring algorithm and the mean ratio method when one or more recalls is available as demonstrated in simulation studies.[137, 138] The population ratio method averages the intake of all participants, generating a single ratio, and then a single score. This results in better estimation of the population average score compared to the simple scoring algorithm, which generates a score for each participant and then averages scores makes statistical sense. Figure 4 graphically compares the calculation methods of the Simple Scoring Algorithm and Population Ratio Method.

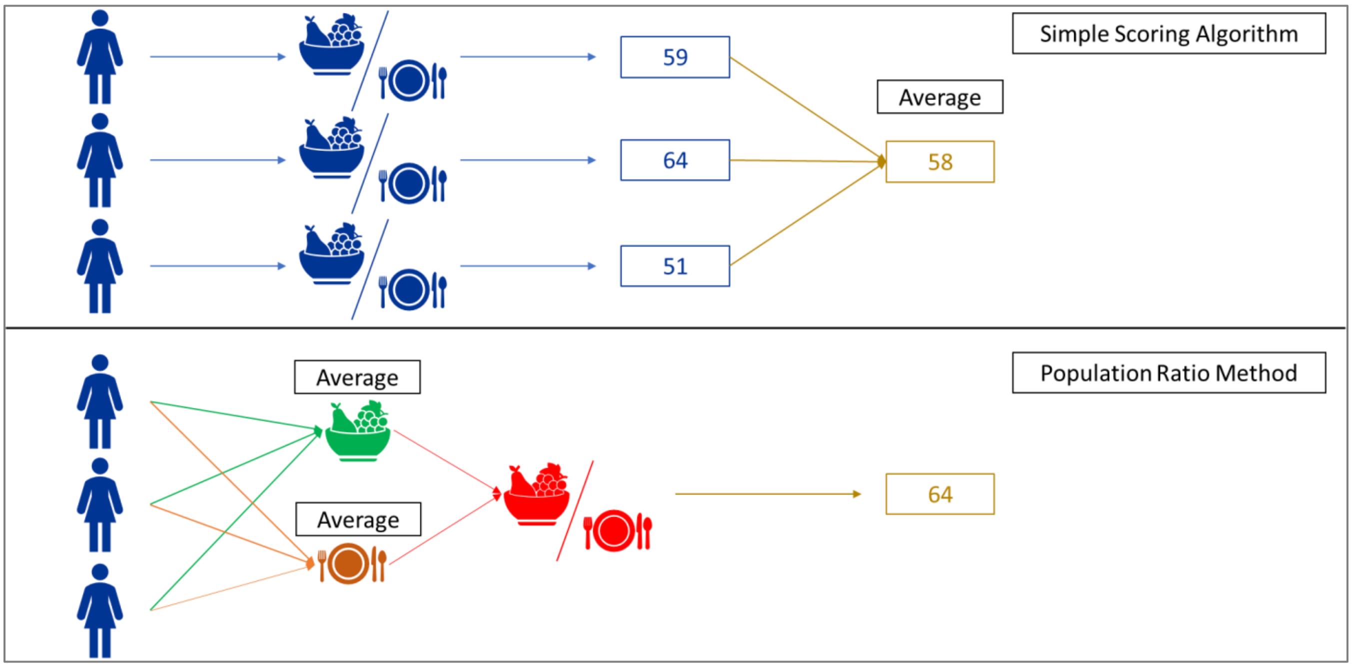


Figure 4: Comparison of the Simple Scoring Algorithm and Population Ratio Methods of Healthy Eating Isdex Scoring

For examining associations between variables as in regression-based analyses, HEI scores for each individual participant are required. The bivariate or simple scoring algorithm are recommended for this purpose with work being done on how to get predicted scores from the multivariate method. For the bivariate method, empirical bayes estimation would be needed to predict intake and then adaptive Gaussian quadrature could be applied to get predicted scores.

How to properly control for measurement error when diet is an independent or response variable needs to be carefully considered as detailed in Keogh et al 2016.[139] Most work has only considered the HEI as a dependent variable in regression analyses. When diet is an exposure variable and measured with error, usually the result will be biased towards the null. However, when diet is an outcome, the bias is likely towards the null when the bias is non-differential but may be away from the null when differential as when intervention participants are aware that improving diet is a goal of the study and report better intake.[139] Such biased reporting has been observed among intervention participants.[140]

As the HEI total score is designed to give an overall representation of diet quality, it is the variable of interest in analyses. The component scores, in and of themselves, are of little interest, but are useful for jointly describing the dietary pattern through visualization in a radar plot. As there are many component scores, which are scores based off ratios, diving deeply into total scores, component scores, and each part of the ratio would require adjustment for multiple comparisons.

In summary, dietary data can be difficult to work with because of both random and systematic error. Questions remain including how to deal with never consumers, for example, vegetarians and vegans who will never contribute to meat, seafood, and/or dairy intake. Modelling never consumers may only be possible with a large number of repeat measures or measured covariates which strongly correlate with being a never consumer.[136] Work continues especially with episodically consumed foods using semiparametric methods of estimation.[141, 142] STRengthening Analytical Thinking for Observational Studies (STRATOS) guidance documents address issues arising from measurement error in epidemiological research which are underappreciated[143, 144] and for which many studies do not properly account.[145] These documents include detailed statistical explanation of the error and practical guidance as to statistical software that can be utilized to correct for it.

1.7 The Relationship between Diet Quality and Disease Risk Factors

1.7.1 Adiposity

Obesity is a major public health concern in the United States with a large and increasing number of people affected. The prevalence of adult obesity has increased from 30.5% in 1999-2000 to 42.4%% in 2017-2018.[146, 147] Poor diet quality is a major correlate of prevalent overweight ($25 \leq BMI < 30$ kg/m^2) and obesity ($BMI \geq 30$ kg/m^2) [41] as well as weight gain over time.[148]

Analysis of National Health and Nutrition Examination Survey (NHANES) data have found significant inverse relationships between quartiles of HEI-2005 scores and overweight/obesity (OR=0.66; 95% CI: 0.57, 0.77) and waist circumference (OR=0.65; 95% CI: 0.56, 0.76).[149] Similarly, a 10-point increase in HEI-1995 score was associated with a 8.3% lower odds of high waist circumference (>40 inches for men and >35 inches for women).[150] Diet quality has also been shown to relate to visceral adipose tissue (VAT), body fat percentage, total body fat, and trunk fat cross-sectionally.[151] Indeed, overall diet quality has been shown to be lower among older adults with obesity who also presented with higher risks of some micronutrient inadequacies compared to peers with a healthy weight according to data from NHANES 2011-2014.[152]

Similarly, in the Multiethnic Cohort (MEC), HEI scores have been associated longitudinally with other measures of adiposity: lower VAT, total body fat, trunk fat, liver fatness, VAT/subcutaneous adipose tissue (SAT) ratio, trunk/leg fat ratio, and percent liver fat.[153]

1.7.2 Other Cardiometabolic Risk Factors

Importantly, diet quality is related to risk factors other than weight. Women with obesity but having ≤2 risk factors: high blood pressure, triglycerides, HDL-C, or fasting glucose had better HEI diet quality compared to women with obesity who had more metabolic dysfunction.[154] Similarly, adults with a least one cardiometabolic risk factor (i.e., overweight/obesity; high triglycerides; low HDL-C; Homeostatic Model Assessment for Insulin Resistance (HOMA-IR) > 2; hemoglobin A1C (HbA1c) > 5.7) had worse HEI-2015 scores than those without risk factors. A total score of ≥64 was associated with having no risk factors.[155]

In the Multiethnic Study of Atherosclerosis (MESA), healthy dietary patterns were related cross-sectionally to cardiovascular disease risk factors including urinary albumin: creatinine ratio, common carotid intima-media thickness, inflammatory markers, and insulin concentrations.[156] Analysis of NHANES data has found significant inverse relationships between HEI-2005 scores and diastolic blood pressure when comparing the highest vs. lowest quartiles of scores (OR: 0.74, 95% CI: 0.63, 0.89).[149] Healthier diet quality is also associated with better muscle strength,[157] and among older adults, poorer diet quality has been associated with frailty.[158]

1.8 The Relationship between Diet Quality and Disease

In epidemiological research trying to establish a relationship between a single nutrient and disease can be difficult. For one, it requires good measurement of the nutrient of interest as well as good measurement of other nutrients for which you may want to control. However, as nutrients can be highly correlated with each other as well as with energy intake and many nutrients may plausibly be considered confounders, determining the independent effect of a single nutrient by controlling for multiple other nutrients may lead to a very small effect with large confidence intervals defying useful interpretation.[10] Because of this difficulty it is sometimes easier to find associations, often stronger associations, between dietary patterns and disease and disease risk factors.

1.8.1 National Health and Nutrition Examination Survey (NHANES)

NHANES is a large epidemiological survey designed to be representative of the non-institutionalized civilian US population and is conducted annually. Dietary data are generally collected using up to two dietary recalls by trained interviewers who utilize food models to increase accuracy of reporting. Laboratory measurements and questionnaires are also available.

In an age-, race-, sex-, and energy-adjusted analysis of variance (ANOVA), statistically, though perhaps not clinically, significant associations between lower diet quality and prevalent diabetes[159] have been observed with a 1.8-point higher score among those without diabetes compared to those with diabetes. When NHANES 2003-2008 data have been linked with mortality data, a statistically significant relationship between diet quality (measured by the Prime Diet Quality Score (PDQS) and HEI-2015) and all-cause mortality has been observed adjusting for age, sex, and race/ethnicity; however, the relationship between HEI-2015 and all-cause mortality was attenuated with additional adjustment for day of week, smoking, alcohol use, physical activity, and BMI (adjusted HR=0.92; 95% CI: 0.84-1.01) but not for the PDQS. Note though that the confidence interval in fully adjusted models for the PDQS touched 1.00 but did not cross; therefore, the distinction between the two indices in results is small. The authors hypothesized that difference by index may have been observed because of suboptimal scoring methods that biased results toward the null.[160]

1.8.2 Atherosclerosis Risk in Communities (ARIC)

The ARIC studied enrolled adults 45-64 years from four communities in North Carolina, Mississippi, Minnesota, and Maryland in 1987-1989. It utilized a 66-line-item food frequency questionnaire to collect data on dietary habits. In ARIC, with over 20 years of follow-up, higher HEI-2015 scores at the initial visit were associated with 16% lower hazard of incident CVD (i.e., coronary heart disease, stroke, or heart failure),[161] 32% lower hazard of cardiovascular mortality, and 32% lower hazard of all-cause mortality when comparing the highest to the lowest quintile.[162] In a similar analysis, higher HEI scores were again associated with incident CVD (less follow-up time than previous analysis); however, 6-year change in diet quality score was not associated with hazard of CVD perhaps because of small changes in diet quality over time (visit 1: 71·0 (SD 8·7), visit 3: 72·9 (SD 8·4)).[161] HEI-2015 scores were not associated with hazard of T2D in this sample in analyses fully adjusted for age, sex, race and center interaction, education, family history of diabetes, family history of CHD/stroke, smoking status, physical activity, alcohol intake, energy, hypertension, hypercholesterolemia, estimated glomerular filtration rate, and BMI.[161]

Diet quality has also been associated with risk of abdominal aortic aneurysm even controlling for time-varying blood pressure with evidence of a potential interaction with CRP level.[163] Principal component analysis in ARIC derived two dietary patterns: prudent and western diets. A prudent diet, characterized by high intakes of whole grains, fruits, vegetables, yogurt, poultry, and fish and seafood, was associated with lower risk of venous thromboembolism over 22 years of follow-up compared to the western dietary pattern.[164]

1.8.3 Multiethnic Study of Atherosclerosis (MESA)

MESA is a multi-site study of non-Hispanic white, African- American, Hispanic, and Asian (predominately of Chinese descent) adults aged 45-84 years which begun in 2000.[165] Dietary data were collected via a 120-item food frequency questionnaire (FFQ) adapted to include Chinese foods and cultural practices. Work from MESA suggests that diet patterns, defined a priori by the researchers, were associated with BMI, waist circumference[156] and T2D. A pattern characterized by consumption of whole grains, fruit, nuts/seeds, green leafy vegetables, and low-fat dairy was associated with a 15% lower T2D risk whereas individual component food groups of the diet patterns were not independently associated with T2D risk. Models were adjusted for energy, study center, age, sex, and race/ethnicity, education, physical activity, smoking status and pack-years, supplement use, and waist circumference.[166]

As discussed previously, stronger relationships can be observed between indices and disease compared to any single dietary constituent and disease. It may be the case that fruit intake alone contributes only a small benefit but combining the benefit of fruit with the benefit derived from other dietary constituents makes a large enough difference to affect risk.

1.8.4 Multiethnic Cohort (MEC)

Perhaps some of the strongest evidence for the diet quality-disease relationship in a US population comes from MEC as it involved very detailed collection of dietary data. In MEC, diet was assessed using a 182-item FFQ which was calibrated in each ethnic-sex group to control for measurement error that would affect risk estimates. Three dietary recalls were collected in a subsample for this purpose. Additionally, the FFQ was designed to include ethnic-specific foods and utilized information from a large recipe database to better assess diet in the ethnic minorities represented in the sample.[167]

MEC consisted of a cohort of whites, Native Hawaiians, Japanese Americans, Latinos, and African Americans living in Hawaii and California aged 45-75 years at enrollment. In this study, lower diet quality as measured by AHEI-2010, aMED, and DASH, but not with HEI-2010, was associated with incident diabetes in specific subgroups (for DASH: white men and women, Japanese American women, and Native Hawaiian men; for AMED and AHEI-2010: white men and women only). Analyses adjusted for age, physical activity, smoking, education, BMI, and energy.[168]

Researchers hypothesized that the ethnic differences in associations might be because of the different cultural ways of eating, indices not constructed with the consumption patterns of ethnic minorities in mind, and/or biologic differences metabolism of glucose or insulin. For example, in a subtraction analysis, researchers found that foods consumed in high amounts and variety among Native Hawaiians (such as red meat, sugar sweetened beverages, and fruit juice) contributed strongly to the association seen between T2D risk and DASH; in comparison, the HEI-2010 does not consider "red meat" consumption specifically in its scoring.[168] Similar results were observed when an updated definition of T2D was applied which made use of administrative claims data in addition to self-reported T2D as opposed to ascertainment via questionnaire only in the previous analysis. There was no adjustment for access to care which could affect the ascertainment of cases.[169]

Controlling for BMI, ethnicity and other factors, HEI-2015 scores were associated with the development of CVD, cancer, and all-cause mortality in MEC over 17-22 years of follow-up in both men and women (gender-specific HRs ranged from 0.75 to 0.84).[170] Also independent of

BMI, HEI-2010 scores accounted for 7.9% of stroke mortality in MEC and was the most predictive of stroke mortality among the diet quality indices tested.[171]

Findings were less consistent for cancer adjusted for age, BMI, diabetes, energy intake, ethnicity, education, marital status, smoking, physical activity, and alcohol as well as hormone replacement in analyses among women. HEI-2015 scores were associated with incident cancer deaths in men (HR: 0.76; 95% CI: 0.70, 0.83) when comparing the lowest and highest quintiles but results among women were not as large (HR: 0.89; 95% CI: 0.81, 0.98). However, for women, the aMED did show a larger relationship with cancer deaths (HR: 0.84; 95% CI: 0.76, 0. 92).[172] The researchers note that some dietary components may play a more important role in certain cancers compared to others, which might help to explain inconsistencies in results.

For colorectal cancer, the relationship between diet quality and survival in MEC was harder to parse with the relationship differing by diet quality index used, ethnicity, gender, and estrogen use. Only the aMED was related to colorectal cancer survival in women as a group. Secondary analyses showed relationships between HEI-2010, aMEd, and DASH with lower CRC mortality only in African American women. Statistically significant inverse associations were seen between indices and mortality among estrogen users but not among non-users with stronger associations when disease was advanced. Results suggest there might be synergistic effects between diet and estrogen use. Differences in scoring, with more emphasis on nuts and legumes in aMED, might also have contributed to the results. However, the study was not without weaknesses such as small sample sizes in some ethnic groups and a single measure of diet at study entry, about 6 years prior; thus, the researchers emphasize the hypothesis-generating nature of this research.[173]

Like in ARIC, improvements in diet quality over 10 years in MEC were small (3.2 HEI-2015 points in men and 2.9 in women). This increase mirrors a general improvement in diet quality of the population seen over time as well as the fact that diet quality is better in older age groups compared to younger age groups.[174] Factors associated with improvement in diet quality included higher education, normal weight, and health-conscious behaviors (e.g., nonsmoking, higher MVPA, and multivitamin usage), which were also generally related to better diet quality cross-sectionally.

1.8.5 European Prospective Investigation into Cancer and Nutrition (EPIC)

Hundreds of reports on the relationship between dietary components and cancer have been published using data from the large (N>500,000) multicenter EPIC study, which utilized country-specific dietary questionnaires calibrated using 24hr recalls in a subsample. Overall, results suggest a protective effect of the Mediterranean diet on colorectal and breast cancer risk with other protective effects observed for certain foods and disease relationships (e.g., fruit and vegetable consumption and colorectal, breast, and lung cancer risk).[175] In the Greek subsample of EPIC, adherence to the Mediterranean diet was associated with reduced hazard of all-cause mortality, coronary heart disease, and cancer controlling for age, sex, BMI, physical activity level, smoking status, education, and waist-to-hip ratio as well as energy intake and consumption of eggs and potatoes, which are not part of the dietary score.[34]

1.8.6 Other Cohort Studies

In the Women's Health Initiative Observational Study (WHI OS), among a cohort of postmenopausal women whose diet was assessed using a FFQ, women in the highest quintile of HEI-2015 scores compared to those in the lowest quintile had 18% and 21% lower risk of all-cause and cancer-specific mortality, respectively, although no association with CVD death was observed.[176] Results were of a similar magnitude in the NIH-AARP Diet and Health Study (NIH-AARP), which enrolled a cohort of AARP members 50-71 years old from 6 states and 2 metropolitan areas, with diet assessed using a 124-item FFQ. Highest vs. lowest quintiles of the HEI-2010 and HEI-2015 score were associated with a 13 to 23% decreased risk of all-cause, cancer, and cardiovascular disease mortality.[177]

1.8.7 Pooled Data and Meta-Analyses

Several pooled analyses and meta-analyses have been conducted to assess the diet quality-disease relationship. In combined analyses from the Nurses' Health Study (NHS), NHS II, and Health Professionals' Follow-up Study (HPFS), a 25-percentile higher diet quality score was associated with 10-20% lower hazard of CVD across various healthy eating patterns including the HEI. An advantage of this analysis is that there was high retention and multiple measurements of diet, which were averaged to better represent long-term dietary habits and minimize within-person variation.[178]

Combining data from 6 prospective cohorts (i.e., MESA, ARIC, Coronary Artery Risk Development in Young Adults [CARDIA], Cardiovascular Health Study [CHS], Framingham Heart Study [FHS], and Framingham Offspring Study [FOS]), those in the highest compared to the lowest quintile of aHEI score had 0.5 to 2.2 more years free of cardiovascular disease.[179] Similarly, the Dietary Patterns Methods Project, which combined data from NIH-AARP, MEC, and WHI-OS, showed that higher diet quality was associated with 11-28% reduced risk of mortality from multiple causes measured using various indices.[29]

Meta-analyses have suggested that diet quality (defined using multiple indices) is related to various health outcomes such as all-cause mortality (RR=0.80), CVD incidence (RR=0.80) and mortality, cancer incidence and mortality (RR=0.86), incidence of T2D (RR=0.81), and incidence of neurodegenerative disease (RR=0.82); however, the authors acknowledge significant heterogeneity from multiple sources is a limitation of such aggregation as well as the limitation inherent in the use of quintiles in analyses.[180] Meta-analyses more limited in scope may be able to assess dose-response relationships between a specific index, such as the relationship found between the dietary inflammatory index and cancer risk in analyses of 44 studies; however, in such analyses heterogeneity is often still present and therefore subgroup analyses are justified.[181]

1.8.8 Summary

As dietary patterns differ according to regional/cultural eating practices, it is important to assess diet quality-disease relationships in diverse samples. While efforts have been made to do so (e.g., MEC and MESA), not all ethnic groups are represented. Additional studies not described here that may be useful to understanding the relationship of diet quality to disease include the MASALA study which enrolled a cohort of South Asian-origin adults[182] and the Singapore Chinese Health Study.[183] While the focus of this section was to describe the relationship between diet quality and major causes of death in the US (e.g. mainly CVD and cancer), in addition, cohort studies have also suggested links between diet quality and incident dementia,[184] respiratory morbidity (e.g., COPD),[185] and chronic kidney disease (CKD).[186]

While measurement error and other biases may temper the strength of our confidence in results, taken together, the large sample sizes, extended follow-up, and general consistency across multiple samples suggest that a diet quality multiple disease relationship is probable and therefore likely worth addressing in many segments of the population (Table 6).

Table 6: Characteristics of Studies and Observed Relationship between Diet and Select Diseases and Mortality

Study (N)	Measurement	Age (years)	Study Start	All-Cause Mortality	CVD	Diabetes	Cancer
NHANES (N~4,000-6,000)	1-2 24HR	≥40; ≥20	2003-2008; 2013-2016	✓*		✓	
ARIC (N~16,000)	66-line-item food frequency	45-64	1987	✓	✓	x	
MESA (N~6,500)	120-item FFQ	45-84	2000			✓	
MEC (N>215,000)	182-item FFQ (calibrated in each ethnic-sex group based on three 24HR)	45-75	1993	✓	✓	✓	✓
EPIC (N>500,000)	Country-specific dietary questionnaires (calibrated using 24HR)	35-70	1992				✓
WHI-OS (N~59,000)	122-item FFQ	50-79	1993	✓	x		✓
NIH-AARP (N~490,000)	124-item FFQ	50-71	1995	✓	✓		✓
Notes: ✓=observed, x=not observed, *=trending in the expected direction							

1.9 Interventions Targeting Diet

Given the rise of chronic diseases in the US and the relation of diet to both risk factors and disease, the need for intervening on diet is clear. First, we will examine the results of two large interventions that explicitly focus on altering the dietary pattern as these interventions are the best placed to improve diet quality.

1.9.1 The Primary Prevention of Cardiovascular Diseases with a Mediterranean Diet trial (PREDIMED)

The PREDIMED trial includes over 6000 older adults with overweight/obesity and at least three criteria of metabolic syndrome. As such, it is the largest trial to date that explores the effect of a Mediterranean style diet on CVD risk. PREDIMED is a multicenter randomized trial that included countries bordering the Mediterranean Sea and countries which do not and have different eating patterns. The trial tested a Mediterranean diet supplemented with extra-virgin olive oil and Mediterranean diet supplemented with mixed nuts compared to a control group. In PREDIMED, diet was assessed using a validated 143-item food frequency questionnaire.[187, 188]

Results showed that both intervention groups had reduced hazard of cardiovascular disease development compared to control over a median of 4.8 years of follow-up. However, this effect may have had less to do with the prescribed Mediterranean diet than the supplemental items provided as differences between groups in consumption were primarily due to the provided items.[188] Nevertheless, improvements in diet quality, defined using adherence to DASH, in PREDIMED over 1 year were associated with reductions in HbA1c, fasting glucose, triglycerides, waist circumference, BMI, non-HDL-C, and systolic and diastolic blood pressure, as well as with an increase in HDL-C. However, it is important to note that improvements in DASH scores were small over one year.[187] This research lends support to the importance of dietary modification for health although it remains unclear whether results can be achieved without supplementation of the diet. Recommendation of a Mediterranean diet style eating pattern and evaluation of adherence to such a pattern have been assessed in non-European cohorts.[189, 190]

1.9.2 Food4ME Trial

The Food4Me study is another European multicenter RCT testing web-based personalized nutrition (PN) advice. The three intervention arms received PN advice based on 1) dietary intake, 2) dietary intake and phenotypic data, or 3) dietary intake, phenotypic data, and genotypic data. Participants within each of the three intervention arms were further randomized to receive either 'low intensity' (PN advice once each at baseline, and months 3 and 6) or 'high intensity' PN (PN advice at baseline and months 1, 2, 3, and 6 in addition to access to an online forum for discussion, recipes, and personalized physical activity feedback) versions of treatment. The intervention arms were compared to a control arm which received conventional non-PN advice. Dietary intake was assessed at baseline, months 1, 2, 3, and 6 using an online FFQ.[191]

Four clusters were identified based on the percent meeting recommendations for oily fish, red meat, whole grains, and fruit/veggies as shown in Table 7. For participants randomized to Level 2 and 3, participants falling into Cluster 4 (not meeting recommendations for oily fish or whole grain intake) had greater improvements in HEI-2010 scores compared to at least one other cluster (characterized by meeting recommendation for oily fish, whole grains, and/or red meat). Improvements in HEI-2010 total score in the study were of the order of ~0 to 8 points depending on cluster and level of intervention. Analyses did not consider intervention intensity but did control for age, sex, BMI, physical activity, smoking, and country.[192, 193] Additional results showed that older adults, women, those with greater self-efficacy for eating healthy foods, and those with lower HEI scores at baseline were more likely to benefit from the intervention (defined as improving the HEI score by ≥5%).[194] This trial suggests that web-based nutrition interventions may successfully alter dietary intake at least in the medium term (i.e., 6 months).

Table 7: Description of Clusters Identified in the Food4Me Trial

% Meeting Recommendations				
Cluster	Oily Fish	Red Meat	Whole Grains	Fruits & Veggies
1	100	46	74	69
2	0	100	100	50
3	0	0	100	48
4	0	50	0	29

1.10 Lifestyle Interventions with Weight Loss Targets

Results from PREDIMED and Food4Me suggest that it is possible to alter diet quality, at least in European populations, although the improvements may be small to moderate. However, neither PREDIMED nor Food4Me targeted participants with overweight and obesity who might benefit from both caloric restriction and improved diet quality. The US Preventive Services Task Force (USPSTF) recommends clinicians offer or refer adults with obesity to intensive, multicomponent behavioral interventions.[195] Many of these weight loss interventions are based on the Diabetes Prevention Program and Look Ahead trials.

Of note, similar lifestyle interventions have been conducted outside the US such as the Finnish Diabetes Prevention Study (DPS)[196] in Finland, Da Qing Impaired Glucose Tolerance

(IGT) and Diabetes Study[197] in China, the Indian Diabetes Prevention Programme (IDPP-1) in India.[198]

The Finnish DPS compared education to nutritionist counseling and supervised exercise with additional optional group sessions, cooking lesson, etc. It found a decreased percent of participants who were sedentary, increased moderate-to-vigorous physical activities minutes, and decreased in energy and saturated fat intake in the intervention group compared to control. Clinical improvements in glucose, cholesterol, triglycerides, higher weight loss, and reduced risk of diabetes development were also observed in the intervention compared to the control.[196] The Da Qing IGT and Diabetes Study compared control to 1) diet, 2) exercise, and 3) diet-plus-exercise intervention. All intervention groups showed reduced risk of developing diabetes compared to control and this result held even when analyses were stratified by BMI < or ≥25 kg/m^2.[197] Despite differences in study populations and intervention designs, all studies suggest that lifestyle modification is both possible and beneficial for the prevention of T2D development in patients at risk.

This section will focus on the studies conducted in the US in detail: the Diabetes Prevention Program (DPP) and Look Ahead. The DPP, often used as the basis for designing interventions, has been shown to be successful at inducing weight loss and preventing the development of T2D.[199, 200] The DPP tested a 12-month intensive lifestyle intervention arm against a medication arm (metformin) and compared to placebo. The intensive lifestyle arm included a 7% weight loss goal based on participant starting weight and attempted to achieve this goal through increasing physical activity, providing education and behavioral support, caloric restriction, and moderating fat intake (≤25% of calories from fat); however, it did not explicitly attempt to change the overall dietary pattern.

Only recently has diet quality change been assessed in this seminal intervention. While results showed improvements in mean AHEI scores among the lifestyle group (4.2 ± 9.0 points) compared to the metformin and control groups (1.2 ± 8.5 and 1.4 ± 8.4, respectively), the improvement was small over 1 year.[201] This may be because only one session addressed diet quality independent of the weight loss goal. As the researchers note, the curriculum focused on decreased fat intake. More updated knowledge would lead to the additional suggestion of altering the composition of fat intake.

The Look AHEAD trial[202] tested the effectiveness of a lifestyle intervention targeting weight loss at preventing cardiovascular morbidity and mortality among individuals with overweight and T2D. Like in the DPP, participants had a physical activity and 7% weight loss goal. Participants similarly had a caloric restriction, total fat, and saturated fat goal and were provided portion-controlled meals. However, while at one year, improvements in the lifestyle arm in macronutrient and food group intake were observed compared to the diabetes support and education arm, a holistic assessment of diet quality was not conducted. Importantly, the greatest improvements in macronutrient and food group intake were observed among those utilizing the meal replacements.[203] While promising, it is unclear how sustainable such changes may be when participants no longer have access to meal replacements.

Given the modest improvements in diet quality, or lack thereof, in the DPP and Look Ahead trials, it should not be taken for granted that behavioral interventions are effective at improving diet quality even when they are successful at inducing weight loss through a focus on caloric restriction. As such, it may be useful to reassess current behavioral interventions so that maximum benefit may be attained by the large number of patients referred to such programs.

1.10.1 Relationship between Weight Loss and Diet Quality Change in Interventions

Given that weight loss can be difficult to achieve and maintain, diet quality may be an important alternate endpoint in weight loss interventions. However, it may also play an underappreciated role in initial weight loss and maintenance of lost weight.

Like in the PREDIMED trial, some evidence has emerged from randomized controlled trials targeting weight of a possible relationship between weight loss and diet quality. Participants with overweight and obesity who were taking medication for hypertension and/or dyslipidemia at baseline and who successfully lost weight after a 6-month intervention, were more likely to retain lost weight over three years if they had better diet quality at baseline and/or improved diet quality during the intervention. This was true among 3 of 4 sex-race groups (except for black men).[204]

Similarly, in another intervention among rural breast cancer survivors, diet quality scores were higher at 18 months among participants who maintained lost weight compared to those who regained lost weight.[205] Too, in the DPP, adjusting for caloric intake and baseline weight, weight loss at one year was associated with decreases in total and saturated fat intake and increases in carbohydrate intake, specifically fiber, which suggests possible independent effects of dietary change on weight loss.[206]

One of the few other studies attempting to answer the question of the relationship between diet quality and weight loss experimentally showed that participants who achieved more than 5% weight loss compared to those who did not, had larger changes in overall diet quality as measured by the HEI-2005.[207] However, the generalizability of the results are limited by a short intervention and follow-up (16 weeks) and small homogenous sample of women (N=66).

Slightly larger studies, (N~100) showed similar associations over 12 months. HEI scores were correlated with the number of nutrition education sessions attended and higher HEI scores were associated with greater weight loss at 4, but not 12 months, in the Weight Optimization Revamping Lifestyle using the Dietary Guidelines (WORLD) Study.[208] Among mothers, but not daughters, changes in diet quality were related to changes in BMI, weight, and waist circumference (separate from the effects of exercise and caloric restriction) in the Daughters and Mothers Against Breast Cancer (DAMES) trial.[209] However, both studies used the HEI-2005 which is aligned with dietary guidelines from several year ago and neither study used preferred methods of HEI calculation.

2.0 Significance of Dissertation Manuscripts

Overall, the field has inconsistently assessed diet quality in weight loss trials leaving significant gaps in the literature. The successful completion of this dissertation will highlight the importance of assessing diet quality. The systematic review (**Manuscript 1**) will help contextualize diet quality improvement in weight loss trials. By looking at diet quality change within and between studies, we may begin to understand components of interventions necessary for inducing diet quality change.

Many weight loss trials rely on time-intensive and expensive standard behavioral treatment where patients often meet with a trained lifestyle coach, individually or in a group, multiple times throughout the year. These treatments can be difficult to scale and have limited reach. There are many patients who cannot or do not want to commit to such intensive treatment. With 96% of Americans owning a smartphone and with little difference in ownership by race/ethnicity, income, or education,[210] mobile health (mHealth) is a promising option for the delivery of weight loss interventions. **Manuscript 2** will assess the effects of an easily adopted and relatively inexpensive behavioral intervention delivered through smartphones on improvements in diet quality. As our study is larger (N=502) and with longer follow-up (i.e., 12 months) than many weight loss studies, it will add significantly to the weight loss literature. Our analyses will provide evidence of the association between changes in diet quality and changes in weight loss which is important as a clinically significant improvement in HEI score has yet to be firmly established. Our study evaluates the effect of the behavioral intervention on diet, an integral component of the weight loss process.

Our proposed research makes use of the HEI in research setting where it is underutilized. **Manuscript 3** attempts to further our understanding of diet quality in interventions by asking if participants can assess their diet quality and improvements in diet quality accurately. This may point to a potentially important barrier to improving diet.

This dissertation work will be a model for other behavioral RCTs in how to assess the impact of their interventions on diet quality. Without knowledge of the extent to which an intervention improves diet quality, we cannot fully assess the adequacy of the dietary interventions delivered.

3.0 Manuscript 1: Healthy Eating Index Diet Quality in Randomized Weight Loss Trials: A Systematic Review

3.1 Abstract

Background: Weight loss interventions focus on dietary and physical activity changes to induce weight loss. Both through weight loss and independent of it, diet quality is important for reducing chronic disease risk. However, if and how diet quality changes over the course of a behavioral intervention is unclear.

Objective: To systematically review the evidence from randomized controlled trials on the effect of behavioral interventions on diet quality as defined by the Healthy Eating Index (HEI) among adults with overweight and obesity.

Methods: PubMed, Ebscohost CINAHL, Embase.com, OVID APA PsycInfo, Scopus, and Web of Science were searched through May 2021. Inclusion criteria comprised randomized controlled trials, a primary or secondary aim of weight loss, a sample of U.S. adults with overweight/obesity, measurement using the HEI-2005, 2010, or 2015, and assessment of the time by treatment effect. Interventions must have included behavioral components and lasted ≥3 months. Risk of bias was assessed using the Cochrane Risk of Bias 2 tool. The systematic review protocol was published on Open Science Framework.

Results: Of 3,707 citations retrieved, 18 studies met inclusion criteria. There was a wide array of behavioral interventions assessed, including in-person and mobile health interventions as well as those prescribing intake of specific foods. Risk of bias in the included studies primarily arose from the measurement of the outcome variable. Sample sizes ranged from 34 to 413

participants. Nine studies used multiple dietary recalls with few using the recommended method of Healthy Eating Index calculation. Changes in diet quality ranged from no improvement to 20-point improvement. More often, improvement was in the 4 to 7-point range.

Conclusions: The evidence for the efficacy of behavioral weight loss interventions for improving diet quality among adults with overweight and obesity is limited, as modest improvements in HEI scores were observed in the reviewed studies.

3.2 Introduction

The diet quality of US adults is poor with worse diet quality seen among those with overweight and obesity.[41, 150] With the prevalence of adult obesity at 42.4% in 2017-2018,[147] many behavioral lifestyle interventions target weight loss through diet and physical activity. Poor diet quality is a major correlate of prevalent overweight and obesity,[41] as well as weight gain,[148] and improving diet quality has been related to weight loss.[207] Through its effect on obesity, good diet quality may reduce the risk of developing type 2 diabetes, hypertension, cardiovascular disease,[211] and cancer[212]. In randomized controlled trials (RCTs), better diet quality has been associated with greater weight loss in the short term[208] as well as weight loss maintenance, independent of caloric restriction.[204] So while the focus on caloric restriction is logical for weight loss,[213] researchers hoping to induce weight loss would do well to alter diet quality in pursuit of this goal.

Assessing diet quality change is important not only because of its relationship to achieving weight loss goals. There is evidence that a high-quality diet is beneficial independent of its effect on weight status. For example, metabolically healthy women with obesity had better diet quality compared to metabolically unhealthy women with obesity.[154] As such, diet quality improvement might provide a complementary endpoint in weight loss trials.

The Healthy Eating Index (HEI) is a valid and reliable measure of diet quality.[37] Each version of the HEI aligns with the corresponding Dietary Guidelines for Americans.[25] This multidimensional score has adequacy (e.g., total vegetables) and moderation components (e.g., sodium). The HEI-2015 assigns a different number of maximum points to each component based on amount of intake (in ounces, grams, or cups) per 1000 calories except for 1) the fatty acids component which is scored as the ratio of polyunsaturated fatty acids and monounsaturated fatty acids to saturated fatty acids, and 2) the added sugars and saturated fats components, which are scored based on percent of energy intake.[25] The best possible diet quality is represented by an HEI score of 100 points. As the average HEI-2015 score among U.S. adults was 59 points in 2013-2014,[214] it is clear diet quality is less than ideal.

To our knowledge, one previous systematic review assessed the use of the HEI as an outcome in research. However, there are significant differences in inclusion criteria between the previously published and current review.[215] For example, the present review is limited to randomized trials and trials specifically targeting weight loss. Such knowledge allows for the assessment of the ability of current behavioral interventions to measure and support diet quality change in a high-risk group. Therefore, the objective of this systematic review was to examine the effect of behavioral interventions on HEI-defined diet quality in randomized controlled trials targeting weight loss among adults with overweight/obesity.

3.3 Methods

Prior to the start of the systematic review, the protocol[216] was published on Open Science Framework. The Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) checklist guided reporting.[217]

3.3.1 Citation Identification

An experienced health sciences librarian (MLK) built search strings for PubMed, Ebscohost CINAHL, Ovid APA PsycINFO, and Embase.com (Table 8) that identified database records in which the instrument name (i.e., Healthy Eating Index) or variants (e.g., HEI) appeared in the title, abstract or other fields (e.g., Tests & Measures field). Using the Cited By and Cited Reference Search features in Scopus and Web of Science, articles citing the primary citations for the HEI-2005,[23, 218] HEI-2010,[24, 38] and HEI-2015[25, 37] were identified. Searches were limited to English language articles published from 2005 to present and were run on April 27, 2020 and re-run on May 26, 2021 (PubMed, Embase) and Mary 27, 2021 (CINAHL, PsycINFO, Scopus, WoS). Additionally, references cited in study reports included in the systematic review were examined.

Database search results were downloaded into an EndNote library and duplicates were removed.[219] Records were uploaded into DistillerSR (DistillerSR, Evidence Partners, Ottawa, Canada), a web-based systematic review software.[220] A workflow was created allowing reviewers to screen records and full-text articles. Additional duplicates were identified in DistillerSR and removed.

Table 8: Search strategies by database for a systematic review of the assessment of Healthy Eating Index diet quality change in behavioral weight loss trials.

Database	Search Parameters
PubMed	The database was initially searched on April 27, 2020 and an update search run on May 26, 2021. "healthy eating index"[Title/Abstract] OR "eating index"[Title/Abstract] OR "hei 20*"[Title/Abstract] OR "hei score*"[Title/Abstract] AND ((2005:2020[pdat]) AND (english[Filter])
Ebscohost CINAHL	The database was initially searched on April 27, 2020 and an update search run on May 27, 2021. healthy eating index* OR "HEI-20*" OR "HEI score*" OR ZQ "healthy eating index*" OR ZQ "health eating index*" Limit applied: English Language Limit applied: publication date 2005 - current
Ovid APA PsycINFO	The database was initially searched on April 27, 2020 and an update run on May 27, 2021. 1. (healthy eating index OR health eating index OR HEI 20* OR HEI score*).ti,ab,id OR (healthy eating index OR health eating index).tm. 2. Limit 1 to english language 3. Limit 2 to yr="2005 -Current"
Embase.com	The database was initially searched on April 27, 2020 and an update run on May 26, 2021. ('healthy eating index' OR 'health eating index' OR 'hei 2005' OR 'hei 2010' OR 'hei 2015' OR 'hei score*') AND [english]/lim AND [2005-current]/py

Scopus	The database was initially searched on April 27, 2020 and a search update run on May 27, 2021. (TITLE("development of the healthy eating index 2005")) OR (TITLE("evaluation of the healthy eating index 2005")) OR (TITLE("update of the healthy eating index: HEI 2010")) OR (TITLE("the healthy eating index 2010 is a valid and reliable measure")) OR (TITLE("update of the healthy eating index: HEI 2015")) OR (TITLE("evaluation of the healthy eating index 2015"))
Web of Science	The database was initially searched on April 27, 2020 and a search update run on May 27, 2021. # 81,176#6 OR #5 OR #4 OR #3 OR #2 OR #1 Refined by: LANGUAGES: (ENGLISH) Indexes=SCI-EXPANDED, SSCI, A&HCI, ESCI Timespan=All years # 71,191#6 OR #5 OR #4 OR #3 OR #2 OR #1 Indexes=SCI-EXPANDED, SSCI, A&HCI, ESCI Timespan=All years # 6314CITED AUTHOR: (Guenther P*) AND CITED WORK: (J NUTR) AND CITED YEAR: (2014) Indexes=SCI-EXPANDED, SSCI, A&HCI, ESCI Timespan=All years # 543CITED AUTHOR: (reedy J*) AND CITED WORK: (J ACAD NUTR DIET) AND CITED YEAR: (2018) Indexes=SCI-EXPANDED, SSCI, A&HCI, ESCI Timespan=All years # 4105CITED AUTHOR: (Krebs-smith S*) AND CITED WORK: (J ACAD NUTR DIET) AND CITED YEAR: (2018) Indexes=SCI-EXPANDED, SSCI, A&HCI, ESCI Timespan=All years # 3601CITED AUTHOR: (Guenther P*) AND CITED WORK: (J ACAD NUTR DIET) AND CITED YEAR: (2013) Indexes=SCI-EXPANDED, SSCI, A&HCI, ESCI Timespan=All years # 2177CITED AUTHOR: (Guenther P*) AND CITED WORK: (J AM DIET ASSOC) AND CITED YEAR: (2008) Indexes=SCI-EXPANDED, SSCI, A&HCI, ESCI Timespan=All years # 1387CITED AUTHOR: (Guenther P*) AND CITED WORK: (J AM DIET ASSOC) AND CITED YEAR: (2008) Indexes=SCI-EXPANDED, SSCI, A&HCI, ESCI Timespan=All years

3.3.2 Inclusion Criteria and Screening

To be included, articles needed to report on a RCT with a primary or secondary aim of weight loss. Other inclusion criteria included evaluation of a group by time interaction and measurement of diet quality using the US version of the HEI-2005, 2010, or 2015. The HEI-1995 does not score on a density basis therefore it was not included in this review.[25] Interventions must have included behavioral components (e.g., dietary prescription, self-monitoring) and lasted ≥ 3 months. Study samples needed to enroll U.S. adults (≥ 18 years) with overweight or obesity (body mass index [BMI] ≥25 kg/m^2) to be included.[221]

Forms for title and abstract and full text screening were piloted prior to use to identify and correct issues. All articles were re-evaluated with updated forms. Two reviewers (JC and HWL) independently screened titles and abstracts for pre-specified inclusion criteria. For records appearing to meet the criteria, the full-text article was obtained. Two reviewers (JC and HWL) then independently screened the full-text articles for inclusion. A search was conducted for published full text articles of conference abstracts that made it to full-text review.

3.3.3 Data Extraction and Management

JC extracted data into pre-specified tables that included information on study design (e.g., number of arms), sample characteristics (e.g., age), intervention components (e.g., duration and frequency of intervention), and results (e.g., p-values). Extracted variables were identified in the protocol.[216] Supplements/appendices associated with the articles, design papers, and primary outcome papers were consulted when data were not available to be extracted from the article included in the review. HWL reviewed extracted data for correctness and marked inconsistencies.

3.3.4 Risk of Bias

Risk of bias was assessed by JC and HWL separately. The Cochrane Risk of Bias 2 (RoB2) tool for parallel group, crossover, and cluster randomized trials was used, as appropriate, with domains including: randomization process, deviations from the intended interventions, missing outcome data, measurement of the outcome, and selection of the reported result. An overall risk of bias was made based on RoB2 rules (e.g., if judged high risk of bias in any one domain, overall judgement was high risk of bias).[222] Disagreements in screening, data extraction, and risk of bias assessment were resolved via discussion (Title/Abstract Screening Kappa=0.85; Full Text Screening Kappa=0.78).

3.4 Results

3.4.1 Study Inclusion

Database searching resulted in 9,135 articles of which 5,513 duplicates were removed. Additionally, 85 articles were identified via searching the reference sections of study reports included in the review. Details on the flow of screening can be seen in Figure 5. Briefly, title and abstract screening of 3,707 articles was completed with 217 full text articles sought for retrieval. Two full text articles could not be obtained.

Full text screening led to the exclusion of 197 articles. The most common reasons for exclusion were not using the HEI-2005, 2010, or 2015 and/or participants not having overweight/obesity. One conference abstract and two full text articles[223, 224] were excluded as they reported partial analyses reported in full in articles included in the review. One community-supported agriculture RCT initially appeared to meet inclusion criteria, but upon closer review was excluded because weight loss was an "exploratory" aim of the study, not a "primary" or "secondary" aim, as required by pre-specified inclusion criteria.[225] Finally, 18 articles[107, 208, 226-241] were included in the systematic review.

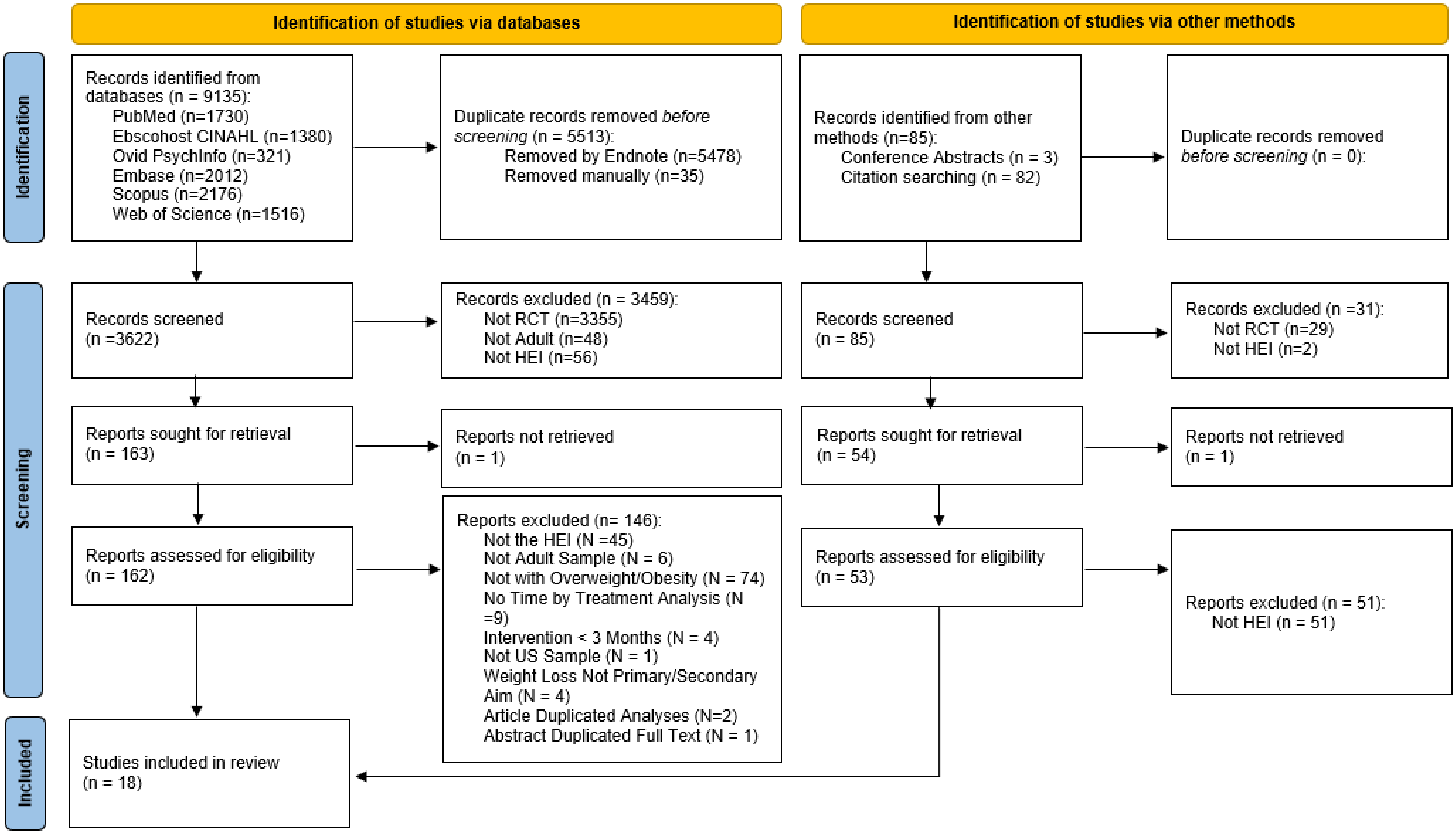


Figure 5: Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) Flow Diagram and Filtering for a Systematic Review of the Assessment of HEI Diet Quality Change in Behavioral Weight Loss Trials

3.4.2 Study Design and Sample

One study used a crossover[235] and one a cluster randomized design[231] with all remaining studies utilizing a parallel groups design (Table 9). Four studies included more than 2 arms.[107, 227, 228, 238] Nine studies had a control group which received minimal guidance or a non-weight loss intervention.[107, 227-229, 232, 238-241] Several studies might be considered comparative effectiveness trials testing slight variations in the basic intervention given to both groups (i.e., delivered in the grocery store vs. clinic,[234] low fat vs. moderate fat prescription,[208] Enhanced Stop Light diet vs. conventional diet[236], active vs. demonstration cooking,[226] with vs. without extra nutrition sessions,[230] with vs. without experiential activity and civic engagement,[231] self-guided vs. interventionist-guided[233]).

Sample sizes ranged from 34[235] to 413[230] participants with most studies having between 100 and 300 participants. Close to half of the studies included only female participants.[208, 227-229, 231-233, 240] One study included only males.[239] Samples included participants who were mostly White, with three studies enrolling mostly or completely Black cohorts.[230, 233, 234] The mean age of enrolled participants varied from young adults[107, 238] in their twenties to adults in their fifties and sixties.[226-228, 230, 231, 233, 235, 237, 239] Many studies enrolled special populations such as breast cancer survivors,[227, 228, 233] women followed through post-partum,[232, 240] persons with human immunodeficiency virus,[241] persons with intellectual and developmental disabilities,[236] and those with pre-existing conditions or risk factors for chronic disease (e.g., migraines, hypertension, hyperlipidemia, pre-diabetes, and/or diabetes).[229, 230, 235, 239]

Table 9: Design and Sample Characteristics of Studies Included in the Systematic Review of the Assessment of Healthy Eating Index Diet Quality Change in Behavioral Weight Loss Trials (N=18)

Author, Year	Study Design	N	Special Population Criteria	Age, years Mean (sd)	Percentage of sample identifying as Female	Education (% ≥4-year college)	SES	Race and Ethnicity	Mean BMI (sd)
Alpaugh et al, 2020[226]	2-arm RCT	56	Cooking ≤3 meals at home/ week	Active: 55(11) Demo: 50 (11)	89%	73%	NR	Active: 100% non-Hispanic, White Demo: 86% non-Hispanic, White	Active: 33.9 (5.8) Demo: 35.5 (5.7)
Anderson et al, 2016[227]	3-arm RCT	100	Breast cancer survivors	Intervention: 59.24 (7.15) Control: 57.90 (7.41)	100%	Intervention: 68.6% Control: 66.7%	NR	Intervention: 94% White Control: 90% White	Intervention: 32.78 (6.40) Control: 33.99 (7.84)
Demark-Wahnerfried et al, 2014[228]	2-site, 3-arm RCT	136	Mothers: Breast cancer survivors Mothers and Daughters: Not currently exercising ≥150 min/week	Mothers: 61.3 (7.4) Daughters: 32.9 (1.4)	100%	Mothers: 34.3% Daughters: 54.4%	Mothers: 31% <$40k per year Daughters: 28% <$40k per year	74% non-Hispanic, White 7% Hispanic, White 18% African American 1% Asian	Mothers: 31.0 (2.6) Daughters: 32.9 (1.4)
Evans et al, 2020[229]	2-arm RCT	110	Neurologist-confirmed migraine	38.8 (8.0)	100%	59.8%	NR	75.6% White 12.2% African American 12.2% Other	35.4 (8.2)
Fitzgibbon et al, 2020[230]	2-arm RCT	413	Symptoms of lower extremity osteoarthritis	67.9 (5.9)	86%	37%	62% <$40k per year	92% non-Hispanic, Black/African American 8% Other	F&S! Plus: 34.7 (0.4) F&S!: 35.0 (0.4)
Folta et al, 2019[231]	2-arm Cluster RCT	194	Sedentary women	58.6 (9.5)	100%	46.4%	50.6% ≤$50k per year	5.4% non-White	35.1 (6.3)
Janumala, et al, 2020[232]	2-arm RCT	210	Singleton pregnancy, Weeks gestation	Intervention: 33.8 (4.0) Control:33.8 (4.7)	100%	Intervention: 81% Control: 86%[242]	65% ≥$75k per year[242]	Intervention: 46% White 24% Black 25% other	Intervention: 30.1 (4.1) Control: 30.7 (5.0)

Author, Year	Study Design	N	Special Population Criteria	Age, years Mean (sd)	Percentage of sample identifying as Female	Education (% ≥4-year college)	SES	Race and Ethnicity	Mean BMI (sd)
			between 9 weeks and 15 weeks 6 days inclusive					5% More than one race 1% Unknown 30% Hispanic 69% Not Hispanic/Latina 1% Unknown Control: 48% White 24% Black 21% Other 8% More than one race 24% Hispanic 76% Mot Hispanic/Latina	
Kwarteng et al, 2021[233]	8-site, 2-arm RCT	246	African-American breast cancer survivors	57.5 (10.1)	100%	38.2%	65.9% <$60k per year	100% Black/African American	36.1 (6.2)[223]
Lewis et al, 2015[234]	2-arm RCT	55	Employees with a doctor visit within 6 months	44.3 (9.2)	64%	40%	56% ≥$50k per year	87% African American	34.8 (5.0)
Njike, et al, 2017[235]	Crossover trial	34	Type 2 diabetes	64.5 (7.6)[243]	41.2%	NR	NR	76.5% White or Caucasian 8.8% Black or African-American 14.7% Hispanic[243]	NR
Psota et al, 2020[208]	2-arm RCT	101	Premenopausal with normal to elevated LDL-C and without elevated Triglycerides	38.9 (0.6)	100%	65%	NR	93% White 2% Black 3% Other	Low Fat: 31.0 (0.6) Moderate Fat: 30.6 (0.6)

Author, Year	Study Design	N	Special Population Criteria	Age, years Mean (sd)	Percentage of sample identifying as Female	Education (% ≥4-year college)	SES	Race and Ethnicity	Mean BMI (sd)
Ptomey et al, 2018[236]	2-arm RCT	150	Mild to moderate IDD and residing in a supported living environment	36.2 (12.0)	56.8%	63.0% High School education	NR	2.7% Hispanic 81.5% non-Hispanic, White 12.3% non-Hispanic, Black 1.4% Asian 0.7% American Indian/Alaska Native 1.4% Two or more races	37.0 (7.8)
Rock et al, 2020[237]	2-arm RCT	100	NA	Pistachio: 55.0 (1.6) Control: 56.2 (1.5)	62%	16.4 years (0.3)	NR	73% non-Hispanic, White 7% Hispanic/Latino 6% African American 4% Asian American 10% Mixed/other	Pistachio: 32.8 (0.6) Control: 32.8 (0.5)
Svetkey et al, 2015[238]	3-arm RCT	365	Verizon or AT&T cellphone user[244]	29.4 (4.3)	69.9%	64.4%	42.1% Income between $25,000 and $49,999 per year inclusive	56.2% White 36.2% Black 7.7% Other 5.8% Hispanic	35.2 (7.8)
Ventura Marra et al, 2019[239]	2-arm RCT	59	Men with hypertension, hyperlipidemia, pre-diabetes, and/or diabetes	59.0 (7.7)	0%	49.2%	49.1% >$75k per year	96.6% White 96.6% Non-Hispanic	36.9 (5.9)
Washburn et al, 2015[107]	3-arm RCT	141	Sedentary[245]	400 kcal: 23.1 (3.0) 600 kcal: 23.0 (3.5) Control: 22.6 (3.0)	50%	NR	NR	16% Minorities	400 kcal: 31.2 (5.6) 600 kcal: 30.6 (3.9) Control: 29.7 (3.8)
Wiltheiss et al, 2013[240]	2-site, 2-arm RCT	400	Given birth ≤6 months and with another child aged 2-5 years	32.6(4.9)	100%	68.9%	56% >$60k per year	78%White/Other 22% Black	39% overweight 61% obese

Author, Year	Study Design	N	Special Population Criteria	Age, years Mean (sd)	Percentage of sample identifying as Female	Education (% ≥4-year college)	SES	Race and Ethnicity	Mean BMI (sd)
Wing et al, 2020[241]	2-arm RCT	40	ART-treated HIV with an undetectable viral load and CD4 count >200 cells/µl	49.9 (8.8)	47.5%	20%	15% >$60k per year	67.5% Caucasian 12.5% African American 7.5% Native American 12.5% Other 80% Non-Hispanic 15% Hispanic 5% NR	34.2 (6.7)
Notes: ART=Antiretroviral therapy; BMI=body mass index (kg/m^2); HIV=Human Immunodeficiency Virus; IDD=Intellectual and developmental disabilities; kcal=kilocalories; LDL-C =Low-density lipoprotein-cholesterol; NA=Not applicable; NR=Not reported; RCT=Randomized Controlled Trial; SD=standard deviation; SES=Socio-economic status									

3.4.3 Study Intervention

The theoretical basis for the intervention design most often referenced was social cognitive theory[208, 227, 228, 230, 231, 233, 236, 238, 240] (Table 10). However, food agency,[226] the transtheoretical model of behavior change,[228, 238] interdependence theory,[228] theory of communal coping,[228] the social ecological model,[231, 233] and social learning theory[208] were also named. Three studies not explicitly stating a theoretical framework mentioned the Diabetes Prevention Program/Look Ahead trails as the basis of the intervention.[229, 232, 241]

The intervention components are provided in Table 10. Types of interventions tested varied, ranging from a supervised exercise intervention[107] to interventions prescribing intake of particular foods (i.e., eggs[235] and pistachios[237]). Both individual and group-based interventions were employed. Ten studies prescribed specific calorie goals;[208, 226-229, 233, 237-239, 241] five studies prescribed fat goals;[208, 226, 227, 229, 241] and five studies prescribed other dietary goals (e.g., fiber intake).[227, 233, 235-237] Many studies included multiple components such as dietary self-monitoring, feedback on self-monitoring, and nutrition education. Educational components varied and could include lessons specific to eating (e.g., serving sizes) as well as lessons focusing on behavioral strategies (e.g., positive self-talk). Six studies included at least one arm with meetings (in-person or virtual) with a coach other than a dietitian[208, 229-232, 236] while an additional eight utilized dietitians.[226, 227, 233-235, 237-239]

Interventions (including maintenance sessions) ranged in duration from 3 months[234, 235, 241] to 24 months[238] with follow-up from 1.5 months[239] after the intervention start to 24 months after the intervention start.[238] The length of time between intervention contacts ranged from daily use of an app (in a remotely-delivered arm)[238] to once every two months[228] and sometimes varied over the course of the intervention.

Table 10: Components of the Intervention and Control of Studies Included in the Systematic Review of the Assessment of Healthy Eating Index Diet Quality Change in Behavioral Weight Loss Trials (N=18)

Author, Year	Frequency	Duration	Theoretical Basis	Intervention	Comparator	Behavioral Components
Alpaugh et al, 2020[226]	Weekly hour-long sessions	6 months	Food Agency[246]	Active Cooking	Demonstration Cooking	Both groups: individualized dietitian feedback; weekly self-monitoring; calorie goal and fat goal (≤25% of calories from fat); exercise goal progressed to 200 min/wk of MVPA; self-monitoring, stimulus control, problem solving, goal setting, relapse prevention, and assertiveness training, daily food, exercise, and weight monitoring Active: 12 cooking classes focusing on sensory analysis, knife skills, and mise en place. Participants worked in pairs to practice skills and prepare a meal.
Anderson et al, 2016[227]	11, 30-minute sessions	6 months	SCT	Dietitian counseling (Individual or Telephone)	Usual Care (brochures)	Goals: Calorie, fat, fiber, added sugar, and fruit and vegetable targets Self-Monitoring: Daily food logging and weekly weighing, Education: Nutrition, exercise, and behavior strategies curriculum
Demark-Wahnerfried et al, 2014[228]	Bi-monthly mailings	12 months	Individual SCT & Transtheoretical model of behavior change Team Same as individual & Interdependence theory & Theory of communal coping	Tailored Diet and Exercise Intervention (Individual or Team)	Attention Control	Individual: tailored diet and exercise intervention including calorie goal; materials to help with self-monitoring of diet and physical activity; goal-setting Team: same as individual but delivered in teams with mothers and daughters encouraged to discuss strategies/barriers
Evans et al, 2020[229]	Weekly meetings	4 months	NR (DPP and Look Ahead)[247]	Behavioral Weight loss	Migraine Education	Weight loss, physical activity, and calorie and fat goals.; Self-monitoring of diet; Strategies for limiting portion sizes, selecting foods, using meal plans and grocery lists, removing high-calorie/high-fat foods from home.

Author, Year	Frequency	Duration	Theoretical Basis	Intervention	Comparator	Behavioral Components
Fitzgibbon et al, 2020[230]	Interventions (90 min) three times per week	2 months	SCT	F&S! Plus	F&S!	F&S! Plus: Sixteen weight and diet-related topics were added to the original F&S! intervention. Diet quality information followed the Group Lifestyle Balance curriculum and the 2010–2015 DGA and US Department of Agriculture My-Plate eating plan. Regular weigh-ins and food diaries. Maintenance Sessions: (Months 3–18) Telephone reinforcement sessions.
Folta et al, 2019[231]	Twice weekly classes and monthly out-of-class meetings	6 months	SEM & SCT	Strong Hearts, Healthy Communities (SHHC)	SHHC condensed (no experiential activity or civic engagement)	Both groups: Healthy eating practices including goals to increase/decrease consumption of certain macronutrients in line with DASH eating plan and the DGA SHHC only: Aerobic exercise, progressive strength training, experiential activity; Discussion of civic engagement to address built environment
Janumala et al, 2020[232]	One-on-one visits to counselors twice monthly with additional weekly telephone and internet contacts until delivery.	Follow-up to 59 weeks post-partum	NR (DPP and Look Ahead)[242]	Lifestyle Intervention	Usual Care (less focus on calorie counting)	60 minute ‘Introduction’; 20 modules that covered nutrition, eating out, cooking, smart shopping, problem-solving, mindfulness, goal-setting, relapse prevention, cravings/hunger management, positive self-talk, and exercise; Self-monitoring of diet and physical activity with tailored feedback.
Kwarteng et al, 2021[233]	Twice-weekly	6 months	SCT and SEM[248]	Interventionist-Guided	Self-Guided	Both groups: 5% weight loss, caloric restriction, increased fruit and vegetable consumption, and increased physical activity goals. Detailed program binder included goal setting, stimulus control, mindful eating, and identifying and addressing barriers to behavior change. At 6 months, monthly newsletters for reinforcing curriculum information, local healthy eating and exercise resources, and participant testimonials.

Author, Year	Frequency	Duration	Theoretical Basis	Intervention	Comparator	Behavioral Components
Lewis et al, 2015[234]	Monthly 60-min meetings	3 months	NR	Grocery Store-based	Clinic-based	Both Groups: Discussion topics: MyPlate and food groups, portion control, label reading and nutritional facts, food prep Social support, self-efficacy, health education, trying new recipes at home
Njike et al, 2017[235]	NA	3 months	NR	Egg consumption	Egg exclusion	Including two eggs per day (10–14 eggs/ week) as part of their otherwise habitual ad libitum diet, while preserving an isocaloric condition relative to the egg exclusion phase. 6 weeks wash out
Psota et al, 2020[208]	Weekly, Bi-weekly, and monthly meetings	12 months	Social learning theory & SCT	Low Fat (20% of calories from fat)	Moderate Fat (35% of calories from fat)	Both groups: 500- to 1,000-calorie deficit; weight loss goal of 10%; 28 1-hour sessions over 12-months: food and behavior related to weight loss and maintenance; daily stretching and five aerobic sessions, two supervised and three on their own, and two unsupervised strength-training sessions per week; aerobic exercise sessions initially lasted 20 minutes and increased to 60-90 minutes. Target heart rate for aerobic exercise: 65%-85%
Ptomey et al, 2018[236]	Monthly meetings	18 months	SCT[249]	Enhanced Stop Light Diet	Conventional diet (MyPlate)	Enhanced Stop Light diet: categories of food—green (low energy, freely consume), yellow (moderate energy, consume in moderation), and red (high energy, consume sparingly). Encouraged consumption of high volume, lower calorie, portion-controlled meals, and fruits and vegetables for first 6 months Self-monitoring of diet and physical activity and monetary incentives for meeting goals for first 6 months. Weight Maintenance diet phase: Months 7-12 Weekly Tracking and Monthly Meetings: Through 18 months
Rock et al, 2020[237]	NA	4 months	NR (although Cognitive Behavioral Therapy techniques used)	Pistachio Consumption	No nut consumption	Both groups: Self-monitoring of dietary and physical activity, using behavior-specific goals; stimulus control and environmental management; problem-solving; and relapse prevention. Caloric Restriction and weight loss goals. PA Goal: 60 min/day of planned aerobic exercise at a moderate or strenuous level. Pistachio Group: Goal: 1.5 oz pistachios/day (42 g/day) or 18% of energy intake; provided recipes and examples of how to include the nuts

Author, Year	Frequency	Duration	Theoretical Basis	Intervention	Comparator	Behavioral Components
Svetkey et al, 2015[238]	Cell Phone: Use of smartphone app with progress check phone call every 6 months. Personal Coaching: 6 2-hour long weekly group sessions led by dietitians. Monthly 20-minute phone contacts	24 months	SCT and the Transtheoretical model	Behavioral Intervention (Cell Phone or Personal Coaching)	Usual care (handouts)	Both intervention groups: Calorie restriction, healthy dietary pattern (DASH), 180 minutes/week of MVPA, limiting alcohol, self-monitoring of weight, diet, and physical activity, feedback, goal-setting. Conscious eating, portion control, priority-setting, social eating, dealing with negative thoughts, stress management, meal planning, triggers and craving, and social support Cell Phone group only: skill building tutorials and live wallpaper, buddy system messages with random pairing every 4 weeks, challenge games, countdown to goals, app-based rewards for positive reinforcement.[244]
Ventura Marra et al, 2019[239]	Weekly	12 weeks	NR	Virtual Dietitian nutritionist support	No weekly support	Both groups: Individualized caloric goal and diet-related education materials and self-monitoring tools Intervention Sessions (intervention only): Nutrition assessment, education and counseling based on the participants diet history, perceived barriers, medical diagnoses, and laboratory values. Patient-led discussions (goal setting, self-monitoring weight change, and overcoming barriers)
Washburn et al, 2015[107]	5 days/wk	4 months	NR	Supervised exercise	Untreated Control	Walking/jogging on motor-driven treadmills; Alternate activities (e.g., stationary biking) was permitted for 20% of sessions

Author, Year	Frequency	Duration	Theoretical Basis	Intervention	Comparator	Behavioral Components
Wiltheiss et al, 2013[240]	Monthly educational kits	8 months	SCT[250]	Family- and Home-based behavioral intervention	Child Reading and Enjoyment Education	Stress management, positive healthy changes in the home, encouraging healthy behaviors, dietary habits, (portion sizes, fruits and vegetable intake, nutritious snacks, food labels, grocery lists) 20 to 30-minute call with trained health coach to review materials Invited to 1 group session led by a registered dietitian
Wing et al, 2020[241]	Weekly lessons	3 months	NR (DPP and Look Ahead)	Interactive multi-media lessons	Usual Care (No behavior change strategies)	Interactive multi-media lessons that targeted behavioral strategies for changing diet and activity to produce weight loss. Calorie, fat, and exercise goals. Self-monitoring of diet and exercise daily with automated feedback weekly.
Notes: AIRC= American Institute for Cancer Research; DASH=Dietary Approaches to Stop Hypertension; DGA=Dietary Guidelines for Americans; DPP=Diabetes Prevention Program; MVPA=Moderate/vigorous physical activity; NR=Not reported; SCT= Social Cognitive Theory; SEM= Social Ecological Model						

3.4.4 Study Measurements and Analysis

Four studies used a food frequency questionnaire,[227, 230, 233, 234] three used dietary records,[236, 239, 241] and one used digital photography and dietary recalls to collect dietary data.[107] Remaining studies (n=10) used dietary recalls with all but one[232] collecting multiple recalls (Table 11). With food frequency questionnaires only the simple scoring algorithm can be utilized for HEI calculation. However, when dietary recalls or records are utilized, there are multiple ways of calculating the HEI. Information on HEI scoring was available for only one study utilizing recalls/records.[239] Authors of other included studies were contacted via email to ascertain the HEI calculation method. Two studies used the preferred population ratio method,[237, 240] one used the mean ratio method,[208] and all other studies used the simple scoring algorithm. Five studies used the HEI-2005,[208, 228, 234, 238, 240] eight the HEI-2010,[107, 227, 229, 230, 232, 233, 235, 236] and five the HEI-2015.[226, 231, 237, 239, 241]

3.4.5 Study Results

Results in Table 11 were categorized by approach as t-test based analyses reported between-group, within-group, and between-and-within group analyses. Regression based approaches reported the time main effect, group main effect, and time by treatment interaction effect. Studies employing regression-based approaches generally adjusted for confounders such as demographics, measures of adiposity, and other factors (e.g., physical function) and sometimes random effects. Reporting of effects and associated p-values was inconsistent, sometimes not reported or reported only as not significant.

Baseline HEI scores ranged from the mid-30s[107] to low 70s.[208, 227] Time main effects/within-group effects ranged from no improvement to a 20-point[239] improvement over the course of the intervention. More often, improvement was in the 4–7-point range, and these changes were statistically significant in nine of eighteen studies.[208, 226, 229-232, 236, 237, 239] Group main effects/ between-group effects were statistically significant in only three studies.[230, 233, 236]

Time by treatment interaction effects/between-and-within group effects were statistically significant for only a few studies.[229, 230, 232, 238] For one study, the significant time by treatment interaction effect was due to differences between groups at 2 months and not at other timepoints.[230] For another study, the time by treatment interaction effect was in an unexpected direction with the control arm showing greater improvement over 24 months than the cell phone intervention arm.[238]

In addition to assessment of the HEI total score, it is recommended that component scores be examined to provide more insight into the dietary pattern with visualization using radar plots as one helpful way of doing so.[36, 37] Data on component scores were available for eight studies[208, 232, 235-237, 239-241] in this review none of which choose to utilize visualizations.

Table 11: Study Measurements and Analysis of Randomized Controlled Trials Included in the Systematic Review of Healthy Eating Index Diet Quality (n=18)

T-Test Based Approach									
	Healthy Eating Index			Analysis					
Author, Year	Measurement of Dietary Intake	Version	Calculation Method	Statistical Model	Baseline HEI score Mean (sd)	Mean Change (sd) Follow-Up	Within-in Group Effect	Between Group Effect	Between and Within Group Effect
Alpaugh et al, 2020[226]	3 24HR collected using ASA-24 (2 weekdays and 1 weekend)	2015 (Mattie Alpaugh, MS, RDN, email communication, July 22, 2021)	Simple Scoring Algorithm (Mattie Alpaugh, MS, RDN, email communication, July 22, 2021)	Repeated measures analysis	Active: 54.93 (2.19) Demo: 52.05 (2.19)	Active: Δ 6.08 (2.62) Demo: Δ 6.23 (2.84) LS Mean (SE) 6 M	Active: p=0.02 Demo: p=0.03	Baseline: p=NS 6 Months: p=NS	p=0.97
Janumala et al, 2020[232]	Single 24HR	2010	Simple Scoring Algorithm (Kathryn Whyte, PhD, RD, email communication, July 15, 2021)	T-test adjusted for unequal variances	Intervention: 55.73 (13.84) Control: 55.82 (16.45) (Pregnancy 9-15 weeks)	Intervention: 61.80 (16.05) to 56.04 (13.14) Control: 54.78 (15.02) to 50.98 (14.78) Pregnancy 35 wks to Postpartum 59 wks	Intervention: 35 weeks: p=0.01 59 weeks: p=0.02 Control: 35 weeks: p=0.62 59 weeks: p=0.49	Baseline: p=NS 35 weeks: NR 59 weeks: NR	Baseline to 35 weeks: p= 0.03 Baseline to 59 weeks: p=0.03

T-Test Based Approach									
	Healthy Eating Index			Analysis					
Author, Year	Measurement of Dietary Intake	Version	Calculation Method	Statistical Model	Baseline HEI score Mean (sd)	Mean Change (sd) Follow-Up	Within-in Group Effect	Between Group Effect	Between and Within Group Effect
Kwarteng et al, 2021[233]	Block 2005 FFQ	2010	Simple Scoring Algorithm	T-test	Intervention-Guided: 65.7 (11.4) Self-Guided: 64.4 (10.8)	Intervention-Guided: Δ6.4 (10.0), Δ5.0 (9.5) Self-Guided: Δ3.3 (10.1), Δ3.8 (10.8) 6, 12 M	NR	Baseline: p=0.38 6-month: p=0.03 12-month: p=0.40	p=NR
Lewis et al, 2015[234]	Block FFQ	2005	Simple Scoring Algorithm	Residualized change approach with analysis of covariance controlling for baseline values of knowledge score, HEI, weight, and other self-reported nutritional values	Store arm: 61.3 (11.9) Clinic arm: 61.9 (8.5)	Store arm: Δ5.0 (NR) Clinic arm: Δ4.5 (NR) 3 M	NR	NR	p=0.80

T-Test Based Approach									
	Healthy Eating Index			Analysis					
Author, Year	Measurement of Dietary Intake	Version	Calculation Method	Statistical Model	Baseline HEI score Mean (sd)	Mean Change (sd) Follow-Up	Within-in Group Effect	Between Group Effect	Between and Within Group Effect
Rock et al, 2020[237]	3 24HR using NDSR 2017 (2 weekdays and 1 weekend)	2015	Population Ratio Method (Martha M White, MS, email communication, August 13, 2021)	T-tests for unequal variances	Pistachio: 60.9 (1.8) Control: 63.5 (1.9)	Pistachio: 72.5 (1.8) to 70.3 (1.9) Control: 69.1 (1.6) to 69.0 (2.0) Mean (SE) 2 to 4 M	Control: $p<0.05$ Pistachio: $p<0.01$	p= NS	p= NR
Wiltheiss et al, 2013[240]	≥2 unannounced 24HR	2005	Population Ratio Method (Cheryl A. Lovelady, PhD, MPH, RD, FADA, email communication, March 23, 2021)	NR, presumably t-tests	Intervention: 65.9 (11.2) Control: 65.0 (11.8)	Intervention: 65.4 (11.1) Control: 66.0 (11.9) 10 M	p=NS	Baseline: p=NS 10 months: p=NS	NR
Wing et al, 2020[241]	Three-day FR (2 weekdays and 1 weekend)	2015	Simple Scoring Algorithm (E. Whitney Evans PhD, RD, email communication, April 1, 2021)	Repeated measure analyses of variance controlling for age	Intervention: 47.9 (11.3) Control: 46.7 (12.5)	Intervention: Δ5.3 (11.8) Control: Δ4.3 (13.4) 3 M	p=0.31	NR	p=0.86

Regression Based Approach									
Author, Year	**Healthy Eating Index**			**Analysis**					
	Measurement of Dietary Intake	**Version**	**Calculation Method**	**Statistical Model**	**Baseline HEI Mean (sd)**	**Mean Change (sd) Follow-Up**	**Time Main Effect**	**Group Main Effect**	**Time x Treatment Interaction Effect**
Anderson et al, 2016[227]	120-item WHI FFQ	2010	Simple Scoring Algorithm	Generalized linear model controlling for baseline HEI	Intervention: 70.17 (8.51) Control: 71.08 (9.27)	Intervention: Δ6.80 (10.06) Control: Δ3.05 (8.03) **6 M**	NR	Baseline: p=0.79	p=0.09
Demark-Wahnerfried et al, 2014[228]	Two unannounced 24HR	2005	Simple Scoring Algorithm (Denise Snyder, MS, RD, LDN, email communication, March 22, 2021)	General linear models	Mothers Individual: 62.6 (9.0) Team: 57.5 (10.7) Control: 58.9 (8.7) Daughters Individual: 53.7 (9.0) Team: 53.7 (10.0) Control: 54.2 (9.3)	Mothers Individual: Δ2.0 (14.0) Team: Δ4.8 (8.2) Control: Δ0.0 (12.7) Daughters Individual: Δ2.8 (10.7) Team: Δ5.0 (14.0) Control: Δ1.6 (12.3) **12 M**	NR	p=NS	Mothers p=0.30 control vs. individual p=0.21 control vs. Team Daughters p=0.74 control vs. individual p=0.45 control vs. Team
Evans et al, 2020[229]	Three nonconsecutive 24HR (two weekdays, one weekend)	2010	Simple Scoring Algorithm (Whitney Evans, PhD, RD, email communication, March 30, 2021)	Linear mixed effects models controlling for weight, weight change, and race/ethnicity	Behavioral Weight Loss: 49.9 (1.7) Headache Education: 54.1 (1.7)	Behavioral Weight Loss: 56.6 (1.8) Headache Education: 54.8 (1.8) LS Mean (SE)**4 M**	Behavioral Weight Loss: p<0.01 Headache Education: p=0.73	NR	p= 0.03

Regression Based Approach									
	Healthy Eating Index			Analysis					
Author, Year	**Measurement of Dietary Intake**	**Version**	**Calculation Method**	**Statistical Model**	**Baseline HEI Mean (sd)**	**Mean Change (sd)** **Follow-Up**	**Time Main Effect**	**Group Main Effect**	**Time x Treatment Interaction Effect**
Fitzgibbon et al, 2020[230]	110-item Block FFQ	2010	Simple Scoring Algorithm	Repeated-measures linear models controlling for iteration, WOMAC physical function score, and BMI	F&S! Plus: 65.9 (0.7) F&S!: 66.7 (0.7)	F&S! Plus: Δ4.7 (0.7), Δ2.0 (0.7), Δ0.6 (0.7), Δ1.0 (0.7) F&S!: Δ2.1 (0.7), Δ0.8 (0.7), Δ1.3 (0.7), Δ0.0 (0.7) Mean (SE) **2, 6, 12 and 18 M**	F&S! Plus: 2 months: p < 0.01 6 months: p < 0.01 12 and 18 months: p=NS F&S!: 2 months: p < 0.01 6, 12, and 18 months: p=NS	2 months: p<0.01 6 months: p=0.24 12 months: p=0.47 18 months: p=0.33	p<0.01 (due to 2-month differences)
Folta et al, 2019[231]	≥2 days of 24HR collected using ASA-24	2015	Simple Scoring Algorithm (Rebecca Seguin-Fowler, PhD, email communication, March 8, 2021)	Multilevel linear regression models controlling for site, baseline HEI, age, marital status, and education	Intervention: 57.0 (1.0) Control: 56.3 (1.3)	Intervention: Δ4.9 (1.4-8.4) Control: Δ1.0 (-2.8-4.8) **6 M** Mean (95% CI)	Intervention: p<0.01 Control: p=0.60	Baseline: p=NS 6m: NR	p=0.12

Regression Based Approach									
	Healthy Eating Index			Analysis					
Author, Year	**Measurement of Dietary Intake**	**Version**	**Calculation Method**	**Statistical Model**	**Baseline HEI Mean (sd)**	**Mean Change (sd) Follow-Up**	**Time Main Effect**	**Group Main Effect**	**Time x Treatment Interaction Effect**
Njike et al, 2017[235]	Three 24HR collected using ASA-24 (two weekdays and one weekend)	2010	Simple Scoring Algorithm (Valentine Njike, MD, MPH, email communication, March 5, 2021)	Generalized linear model controlling for age, race, gender, compliance, and treatment sequence	Egg Inclusion: 52.9 (11.0) Egg Exclusion: 52.9 (11.0)	Egg Inclusion: Δ-0.1 (11.4) Egg Exclusion: Δ-3.5 (12.7) **3 M**	Egg Inclusion: $p=0.93$ Egg Exclusion: $p=0.12$[243]	Baseline and 12 weeks: both $p=1.00$[243]	$p=0.26$
Psota et al, 2020[208]	3 Unannounced, nonconsecutive 24HR (two weekdays, one weekend)	2005	Mean Ratio method (Diane C. Mitchell, MS, RD, email communication, July 23, 2021)	Mixed model	Low Fat: 71.4 (1.3) Moderate Fat: 70.2 (1.3)	Low Fat: 77.7 (1.4) to 75.0 (1.3) Moderate Fat: 77.9 (1.5) to 76.5 (2.1) Mean (SE) **4 to 12 M**	$p<0.05$	p=NS	p=NS
Ptomey et al, 2018[236]	Proxy-assisted 3-day FR (2 weekdays and 1 weekend)	2010	Simple Scoring Algorithm (Lauren Ptomey, PhD, RD, LD, email communication, March 5, 2021)	General linear mixed modeling for repeated measures controlling for age, sex, race, education level, and support level	Enhanced Stop Light Diet: 44.9 (11.0) Conventional Diet: 49.2 (12.2)	Enhanced Stop Light Diet: 48.9 (11.5) to 49.8 (11.7) Conventional Diet: 52.8 (10.9) to 51.7 (10.0) **6 to 18 M**	Combined time effect (baseline to 18 months): $p=0.01$ Enhanced Stop Light Diet: 6 months: $p=0.05$ 18 months: $p=0.38$	Baseline: $p=0.03$ 6 Months: $p=0.08$ 18 months: $p=0.42$	$p= 0.17$

Regression Based Approach									
	Healthy Eating Index			Analysis					
Author, Year	**Measurement of Dietary Intake**	**Version**	**Calculation Method**	**Statistical Model**	**Baseline HEI Mean (sd)**	**Mean Change (sd) Follow-Up**	**Time Main Effect**	**Group Main Effect**	**Time x Treatment Interaction Effect**
							Conventional Diet: 6 months: p=0.22 18 months: p=0.17		
Svetkey et al, 2015[238]	2 24HR collected using ASA-24	2005	Simple Scoring Algorithm (Laura Svetkey, MD, email communication, March 22, 2021)	Constrained longitudinal data analysis model controlling for obesity status and sex	Cell Phone: 51.6 (4.2) Personal Coaching: 50.8 (3.6) Control: 50.7 (4.4)	Cell Phone: Δ2.39 (NR) to Δ2.22 (NR) to Δ0.88 (NR) Personal Coaching: Δ3.54 (NR) to Δ1.73 (NR) to Δ2.09 (NR) Control: Δ2.76 (NR) to Δ2.50 (NR) to Δ2.81 (NR) **6, 12, 24 M**	NS	NS	24 months Cell Phone vs. Control p=0.04 All other p=NS
Ventura Marra et al, 2019[239]	4-day FR (3 weekdays and 1 weekend)	2015	Simple Scoring Algorithm	General linear mixed model	Intervention: 51.0 (10.9) Control: 51.1 (14.0)	Intervention: 70.6 (14.3) to 71.3 (13.9) Control:	p<0.01	p=0.63	p=0.11

Regression Based Approach									
	Healthy Eating Index			**Analysis**					
Author, Year	**Measurement of Dietary Intake**	**Version**	**Calculation Method**	**Statistical Model**	**Baseline HEI Mean (sd)**	**Mean Change (sd)** **Follow-Up**	**Time Main Effect**	**Group Main Effect**	**Time x Treatment Interaction Effect**
						61.2 (15.6) to 63.9 (14.8) **1.5, 3 M**			
Washburn et al, 2015[107]	7-day digital photography & 24HR	2010	Simple Scoring Algorithm (Richard Washburn, PhD, email communication, March 5, 2021)	General linear mixed model controlling for age and sex	Scores averaged across all time periods <u>400 kcal/session:</u> 37.6 (8.9) <u>600 kcal/session:</u> 35.6 (8.4) <u>Control:</u> 36.7 (8.5)		p=NS	p=NS	p=NR

Notes: Δ=change; 24HR= 24-hour recall; ASA=Automated Self-Administered (recall system); FFQ=Food Frequency Questionnaire; FR= food record; HEI=Healthy Eating Index; kcal=kilocalories; NA= Not applicable; NDSR=Nutrition Data System for Research; NR=Not reported; SD=standard deviation; SE=standard error; WHI=Women's Health Initiative

Notes: Depending on the analysis, p-value is either the time x treatment interaction (e.g., mixed model) or treatment difference in change score (e.g., t-test). Regardless, the meaning is the same.

3.4.6 Risk of Bias

Figure 6 summarizes the risk of bias assessment for included studies. The risk of bias arising from the randomization process (Domain 1) and deviations from the intended intervention (Domain 2) were low for all but two[236, 241] and three studies,[227, 234, 235] respectively. Because it is rarely feasible in behavioral interventions to blind participants to treatment, all studies were potentially biased for this reason. However, as most of the studies did not have specific diet quality goals, the bias to the outcome measure imposed by non-blinding was judged minimal. Little information was provided on potential deviations from the intervention protocol; however, adherence to the behavioral components of the intervention and retention were discussed. For the cluster-randomized trial,[231] the risk of bias arising from the timing of identification or recruitment of participants was judged low. For the crossover randomized trial,[235] the risk of bias arising from period and carryover effects was judged low.

One study[227] was deemed high risk of bias due to missing outcome data (Domain 3) which was determined via assessment of amount of complete data, analysis methods (e.g., sensitivity analyses), examination of the CONSORT figure, and differences between treatment groups in the amount of missingness. Amount of complete data ranged from 59.4% (with missing data imputed)[208] to 94.9%.[239] Most studies had greater than 80% retention at one or more follow-up timepoints.[227, 228, 230, 233-239, 241] Measurement of the outcome (Domain 4) was less than ideal (n=15 high risk)[107, 208, 226-230, 232-237, 239, 241] because the choice of dietary collection method was not well-suited for interventional research.[251]

One study was judged high risk of bias for the Selection of the Reported Result (Domain 5) as the study planned to use the Alternate Healthy Eating Index but reported HEI results.[235] Because of changes in scoring standards (e.g., HEI-2015 splits into two components the ‘empty calories' component of HEI-2005 and 2010), the choice of HEI version should be justified. Although not affecting the risk of bias assessment, as it is unlikely the the choice of HEI version would have influenced the results, three studies used an older version of the HEI without justification.[226, 234, 238] Five studies were judged as presenting some concerns[208, 230, 232, 237, 238] because diet quality change was not mentioned as an aim of the study on the clinicaltrials.gov webapge and/or in the introduction to the manuscript. According to clinicaltrials.gov, only three studies mentioned diet quality assessment as an aim.[226, 234, 239]

Figure 6: Assessment of bias for studies included in the systematic review of the assessment of Healthy Eating Index diet quality change in weight loss trials using the Cochrane Risk of Bias 2 tool (n=18)

3.5 Discussion

3.5.1 HEI Score Change

In all studies, diet quality was in need of improvement with baseline HEI total scores less than the 74 that would meet Healthy People 2020 objectives.[39] Although it is unclear what a clinically significant improvement in HEI score is, a meaningful difference between groups may be five to six points.[36] As such, 13 studies might have come close to achieving clinical significance.[208, 226-234, 237, 239, 241]

Generally, in studies where comparison groups received standard behavioral treatment components,[208, 226, 230, 231, 233-236] there were similar changes to those seen in the intervention arms. However, among comparison groups receiving only limited treatment (e.g., brochures) or among no-contact controls (or controls receiving a non-weight loss intervention) [107, 227-229, 232, 237-241], there was usually little to no change over time.

The largest improvement in diet quality (~20 points) was in a pilot study where participants worked weekly with a dietitian.[239] While this was one of the most intensive interventions included in the review, the control group, which had a calorie goal and self-monitored, also achieved diet quality improvement of about 10 points. Therefore, the magnitude of effect may have had more to do with the enrollment of highly motivated individuals and with one of the shortest follow-up periods (i.e., 3 months) than with dietitian exposure as other studies employed dietitians with more modest results.

Despite the similarity in intervention to a study prescribing pistachio consumption[237] which had the second largest change (~10 points) in diet quality, one of the studies with no change prescribed egg inclusion or exclusion to the diet.[235] The reason for the differing results may be that the egg trial did not include standard behavioral treatment components such as self-monitoring, caloric restriction, and physical activity goals, which were part of the pistachio study. Another difference was that including pistachios in the diet improved scores for the fatty acid ratio and for seafood and plant proteins, as would be expected. The pistachio study also had a short follow-up (i.e., 2-4 months).

A lack of explicit focus on modifying the diet may be a reason for small/moderate observed improvements in diet quality. Indeed, one researcher hypothesized that their focus on caloric restriction may have been the reason for no diet quality change.[240] Lack of engagement with the intervention, not enough elements of the intervention specifically addressing diet quality, or too short of an intervention were other reasons hypothesized by researchers for lack of improvement in diet quality.[230, 238]

Effects of baseline HEI scores or sample demographic characteristics on HEI improvement were difficult to separate from effects of intervention components, intervention length, and follow-up. However, factors like these have been suggested to be important in a European multi-center trial of a personalized nutrition intervention, which found older adults, women, and those with lower HEI-2010 scores at baseline were more likely to improve HEI-2010 score by $\geq$5%.[194]

Generally, the shorter the follow-up time, the larger the effect as diet quality as improvements diminished over time in studies with multiple follow-up timepoints. For example, in one study there was a 5-point improvement from baseline to 2 months; however, mirroring similar difficulties with maintaining weight loss, improvements were only 2-points and 1-point at 6 and 12-18 months, respectively.[230] Although adherence and retention were not markedly low in included studies, given the behavioral nature of the interventions, it is likely that adherence to nutrition components of interventions and the number and type of nutritional components is important. For example, in one study,[208] attendance of nutrition sessions, was positively associated with HEI-2005 scores.

Generally, studies in the review with more behavioral strategies had better HEI outcomes than studies with limited components. This is consistent with other systematic reviews that found goal setting and self-monitoring were important behavior change techniques utilized in interventions effective at altering physical activity and healthy eating among adults with overweight/obesity.[252] Another important strategy might be the provision of feedback. A short pilot study not included in the review showed dietary monitoring improved over eight weeks among those using electronic forms of self-monitoring compared to paper-and-pencil; however, among Lose It app users who were not provided dietary feedback, diet quality decreased while among groups using the notepad on the phone and paper-and-pencil, who did receive feedback, diet quality increased.[253]

Finally, studies utilizing mailings[228] or apps even with support from a partner[238] generally showed smaller magnitudes of change than studies with coaches. This between-study difference is similar to the difference seen between groups when the intervention was interventionist-guided (~6.4 points) vs. self-guided (~3.3 points).[233]

3.5.2 Measurement of Diet

Due to the complexity of assessing usual dietary intake, methodological issues limit the interpretation of, and confidence in, current results. While there was no difference in collection of dietary data between intervention and control groups, we cannot rule out differential reporting bias as participants in the intervention groups may have self-reported more desirable dietary intake thus biasing the results away from the null. Although we do not strongly suspect differential reporting bias, especially in studies where there was little contact with investigators, it is worth bearing in mind given the modest diet quality improvements observed.

While no self-reported dietary collection method could be said to be without bias, studies utilizing multiple unannounced non-consecutive 24-hour dietary recalls that included both weekday and weekend records were considered the least at risk of bias. Eating patterns on consecutive days are less likely to capture variation in diet[123] and as weekday and weekend eating tend to be different from each other.[254]

Recalls that were not unannounced along with dietary records were judged at more risk of bias due to the potential for reactivity. This can occur when participants change their eating behavior due to the awareness that their eating is being measured; therefore, the recall/record is not reflective of their true usual intake.[124, 255] Digital photography offers an interesting new method of assessing intake as dietitians and/or computers, not participants, code the amount of food consumed; however, this method is still limited by the possibility of reactivity.[256] Food frequency questionnaires were also judged at more risk of bias because they are semi-quantitative in nature[124] and more subject to systematic bias.[129]

3.5.3 Calculation of Healthy Eating Index

An appropriate choice of calculation method is dependent on the purpose of the study.[36] For assessing the effect of an intervention on diet quality, the population ratio, bivariate, or multivariate methods are recommended.[36] As the bivariate[133] and multivariate[135] methods are computationally intensive and require large datasets, it is unlikely any of the studies included in this review would have been able to use such methods.[36] Therefore, the recommended method of calculation would be the population ratio method. When one[138] or more[137] recalls are available, the population ratio method performs better than the simple scoring algorithm at estimating a population's mean HEI score. However, almost all studies used the simple scoring algorithm. Detailed statistical and practical considerations for calculation have been described elsewhere.[36, 132] Additional considerations such as truncation might also be considered.[16]

3.5.4 Strengths and Limitations

A strength of this review was having two reviewers independently complete screening and risk of bias assessment. Additionally, re-running database searches and conducting searches outside of databases were important for identification of additional articles.

A limitation of this review is that for comparability purposes, we focused on a single dietary index. Many dietary indices share similar components[26, 29] although, for example, they may differ in their treatment of energy and determination of cut points for healthful intake.[14] Other behavioral interventions have assessed diet quality change using the Alternate Healthy Eating Index,[201] adherence to the Dietary Approaches to Stop Hypertension,[257] and Diet Quality Index-revised.[258, 259] A future review using multiple indices may be helpful to understand dietary change more holistically in weight loss interventions. A final limitation is that heterogeneity in intervention components precluded the conduct of a meta-analysis.

3.5.5 Recommendations for Future Research

With the large burden of death from chronic diseases in the US,[260] the need for intervening on diet is clear. Diet quality has been shown to relate to many chronic diseases both cross-sectionally and prospectively[159, 161, 180] with improvements in diet quality projected to be able to significantly decrease the prevalence of chronic diseases.[261] The US Preventive Services Task Force recommends clinicians refer adults with obesity to intensive, multicomponent behavioral interventions.[195] As such, it is important to assess the ability of interventions to produce meaningful and sustainable diet quality improvements so practitioners may make referrals confidently.

Interventionists may consider designing interventions with an eye toward improving diet quality, not simply toward weight loss. One important consideration is what components of diet are best to target. Among individuals with excessive energy intake, focus on improving intake of refined grains, added sugars, and/or saturated fats would lead to a reduction in energy consumption thus improving scores on all components that are scored based on a ratio of intake to energy.[25]

Vital to the mission of improving diet quality is a thorough understanding of the complexities of dietary measurement.[143, 144] Journal editors might require information on HEI calculation be provided in manuscripts and assign a reviewer with a strong quantitative/statistical background. Authors and reviewers might consult an available checklist for using the HEI in research.[36]

As more researchers begin to assess change in diet quality in behavioral interventions, a next step would be to relate changes in diet quality to changes in weight, blood pressure, lipid profiles, and other risk factors. A few studies have looked at the relationship between observed changes in diet quality and changes in weight with differing results.[208, 227, 229]

3.5.6 Conclusions

Despite the ubiquity of weight loss interventions and recognition that diet is key to weight loss, few randomized controlled trials have assessed change in diet quality. While this review suggests it may be possible to intervene on diet quality, the evidence for how to do so is not strong. Assessment of diet quality change may be considered an important goal of weight loss interventions, particularly in se interventions with an emphasis on dietary modification.

4.0 Manuscript 2: Effect of an mHealth Weight Loss Intervention on Healthy Eating Index Diet Quality: The SMARTER Randomized Controlled Trial

4.1 Abstract

Objective: Dietary modification is key to weight loss. This secondary analysis of a randomized weight loss trial assessed whether self-monitoring with personalized feedback (SM+FB) versus self-monitoring alone (SM) resulted in improved diet quality.

Methods: Adults with overweight/obesity (N=502) self-monitored diet, physical activity, and weight. Dietary feedback was based on reported energy, fat, and added sugar intake. Diet was assessed using 24-hour recalls which were used to calculate Healthy Eating Index 2015 (HEI-2015) total scores. Higher scores represent better diet quality.

Results: The sample was mostly female (78.9%) and white (85.4%). At baseline, HEI-2015 total scores and bootstrapped 95% confidence intervals were similar by treatment group (SM+FB: 63.11 [61.19-64.6]; SM: 61.02 [59.39-62.34];]) with little improvement observed at 6 months (SM+FB: 65.42 [63.98-66.83]; SM: 63.32 [61.87-64.73]) or 12 months (SM+FB: 63.94 [62.04-65.75] SM: 63.56 [61.48-64.98]) and no differences between groups. However, among those who lost ≥5% of baseline weight by 12 months, HEI-2015 scores improved (baseline: 62.00 [59.62-63.69], 6 months: 68.02 [66.29-70.67], 12 months: 65.93 [64.00-67.91]).

Conclusions: Diet quality was less than ideal with small improvements over time in both SM and SM+FB groups; however, among those who lost weight, diet quality improved. Future interventions might provide more targeted nutritional content.

4.2 Introduction

Obesity rates in the United States are high and continue to rise.[147] As such, extensive research has been conducted developing and testing behavioral interventions for weight loss. Diet and exercise are recognized as key components of standard behavioral weight loss programs with the US Preventative Services Task Force recommending such multicomponent interventions to adults with obesity.[195] However, many studies explicitly focus goals on energy restriction and low/moderate fat intake. While nutritional counseling in interventions may discuss other aspects of diet, such as increasing fruit intake, it is often couched in terms of helping with the energy and fat restriction goals. Few interventions report on dietary changes holistically; therefore, it is unclear if and how weight loss interventions affect diet quality.

Diet quality represents the healthfulness of an individual's dietary pattern. Poor diet quality is a major correlate of prevalent overweight and obesity[41] as well as weight gain over time.[148, 262] In randomized controlled trials, improvements in diet quality have been shown to relate to weight loss separate from the effect of energy restriction.[201, 209] Diet quality has also been shown to relate to weight loss maintenance post intervention.[204, 205]

Importantly, diet quality has also been shown to relate to cardiometabolic risk factors other than weight[41, 153] and has been shown to relate to chronic disease independent of its effect on weight.[263] Indeed, women with obesity who have better diet quality are more metabolically healthy than those with poor diet quality.[154] Since weight loss can be difficult to achieve and weight regain is common,[264] diet quality change may provide an important additional endpoint for assessing the effectiveness of interventions for chronic disease prevention.

Additionally, the provision of personalized dietary feedback may be particularly important for diet quality improvement. In a small pilot study among participants self-monitoring using the

Lose It app, who were not provided dietary feedback, diet quality worsened over 8 weeks. This was in comparison to participants using the Notepad app on the phone or paper-and-pencil methods of self-monitoring who did receive feedback and who improved diet quality.[253]

Therefore, we aimed to examine the effect of a mHealth dietary intervention of self-monitoring and personalized, automated feedback compared to self-monitoring alone on diet quality over 12 months among adults with overweight or obesity. We hypothesized that the provision of feedback would result in improved diet quality over self-monitoring alone. Our second aim was to assess the relationship between diet quality improvement and weight loss with the hypothesis being that we would observe greater diet quality improvements among those with clinically meaningful weight loss compared to those without. Besides establishing the importance of dietary feedback in a remote, scalable intervention, such an examination might help identify how the intervention can be refined for maximal benefit.

4.3 Methods

The SMARTER randomized controlled trial design as well as the primary outcome (i.e., change in weight) have been described elsewhere.[265, 266 267] Briefly, SMARTER randomized participants with overweight or obesity with equal allocation to either a group which received individualized feedback messages based on self-monitoring data (SM +FB) or to a self-monitoring only comparator (SM) over 12 months. Both groups were given calorie, fat gram, and physical activity goals. At baseline all participants, attended a 1:1, 90-minute dietary counseling session with a master's level registered dietitian with prior experience in standard behavioral treatment. Both groups were instructed to weigh themselves daily on a digital scale, record all foods and drinks in the Fitbit food diary, and wear a Fitbit activity tracker to monitor physical activity. Participants were recruited from the greater Pittsburgh, Pennsylvania area and provided informed consent. Neither assessors nor participants were blinded to treatment assignment due to the behavioral nature of the intervention.

Dietary feedback messages were delivered to a study-specific smartphone app up to three times daily while physical activity and weight messages were sent 3-4 times per week and once a week, respectively. Although there was no specific diet quality goal, suggestions to eat better were inherent in the feedback messaging the intervention group received (e.g., "A balanced breakfast includes different food groups, for example whole grain toast, nut butter, and fruit."). The type of message participants received was determined by algorithm conditions described previously.[265] Briefly, consideration of the prescribed caloric and fat goals as well as added sugar intake were used to select appropriate messages.

Most of the over 2000 unique dietary feedback messages in the message library focused on energy, fat and added sugar intake, as well as the importance of logging foods. Table 12 provides examples of messages that address each component of the Healthy Eating Index-2015 (HEI-2015). The HEI-2015 aligns with the Dietary Guidelines for Americans (DGA) 2015-2020 and was used as the measure of diet quality in this study.[25] Importantly, while some components were never addressed, such as sodium, there were multiple possible messages addressing other components (e.g., the word "fruit" appears in over 100 unique messages).

Table 12: Example Dietary Feedback Messages Addressing Components of the Healthy Eating Index-2015

Adequacy Components	**Example Message**
Total Fruits	Eating enough for breakfast plays a big role in energizing your day! If you already ate breakfast, you could **choose some fruit for a snack.**
Whole Fruits	Do you like juice? Juice is a concentrated source of sugar. There are at least six oranges in a one cup of orange juice. **Choose to eat the whole fruit instead.** It will offer more filling fiber and nutrients found in the pulp and skin.
Total Vegetables	Choose foods lower in fat tonight to stay closer to your fat gram goal! **Steamed veggies or a big salad could be good options** to incorporate.
Greens and Beans	Fat intake is looking good! Take a moment to plan low calorie foods for this afternoon. A lean meat or **beans with steamed vegetables are good options.**
Whole Grains	If you are still under your calorie goal, you have some room for healthy fats! Nut butter on a **whole grain cracker or bread might be a good option.**
Dairy	Excellent job recording food intake. **Sugars look high. Some could have come from milk, yogurt**, sweets, and beverages. Can you identify where yours came from today?
Total Protein Foods	Way to self-monitor throughout the day. Sugars are higher today. Choose low-sugar, **high-protein foods such as eggs, meat, or hummus** with vegetables to snack on this evening.
Seafood and Plant Proteins	You are doing amazing recording, and your calories are on track. You could add some fat grams- **if you like fish, seafood can be a great way to add healthy fats to your diet**. If you don’t like seafood, think about **plant-based fats such as those found in nuts and avocados.**
Fatty Acids	Calories are on target! Fat grams are higher than your goal. Make swaps by **selecting lean protein sources where you may have had fatty protein sources**, or vegetables where you may have had cheese
Moderation Components	**Example Message**
Refined Grains	You are a self-monitoring pro! Take a peek at your log, calories are above your goal range and fat grams are low. **Swapping something like pasta** for a healthy salad with oil-based dressing could balance your intake and help you to meet both goals!
Sodium	No messages
Added Sugars	Are you drinking **sweetened beverages**? Did you know that one 16 fluid ounce bottle of soda can contain 13 teaspoons of sugar, whoa!
Saturated Fats	Calories are on target, while fat grams are a bit low for this time of day. If you are **avoiding saturated fat (e.g., butter, bacon)** to keep your calories in check, remember that healthy fats (fish, nuts, avocados) can also satisfy you and fuel your body. If you choose the right portion size, your calorie intake should be fine.

4.3.1 Measures

Demographic characteristics (e.g., race and ethnicity, income, education) and some clinical characteristics (i.e., self-reported high blood pressure, high cholesterol, high triglycerides, and smoking status) were self-reported at baseline. Height, weight, waist circumference, and blood pressure were measured by trained staff at baseline and body mass index (BMI kg/m^2) was calculated based on weight and height measurements. At-home weight data from the WIFI-enabled scale was used in lieu of staff-collected data after the start of the COVID-19 pandemic in the US (March 2020).

Dietary data were collected at baseline, 6-, and 12-months on two separate days, to minimize within-person random error using the Automated Self-Administered 24-hour recall (ASA-24) system managed by the National Cancer Institute.[113] ASA-24 performs well compared to interviewer-administered recall[114] with computer prompts imitating the multi-pass method. In order to minimize the potential for issues with usability, participants completed their first dietary recall while staff members trained in dietary recalls were present to answer questions. For subsequent recalls, which could be completed remotely, participants could reach out to staff for assistance.

HEI-2015 scores were calculated from dietary recalls. The HEI-2015 has demonstrated construct validity, reliability, and criterion validity[37] and is consistent with other dietary indices.[29] The HEI-2015 includes 9 adequacy and 4 moderation components. For most components, intake per 1,000 calories is scored. Values between the minimum and maximum score are scored proportionally. Component scores are summed to create an HEI total score with 100 being the best possible score.[25] Because the HEI is density-based, the correlation between HEI diet quality and diet quantity is low, suggesting a desirable independence between measures.[37] The average HEI-

2015 score in the general population is 59, [40] well below a score of 74 which would satisfy Healthy People 2020 objectives.[39]

There are various methods of HEI calculation. As the bivariate[133] and multivariate[135] methods require sufficiently large datasets, these methods were not viable for us in our sample. Therefore, HEI-2015 total and component scores were calculated using the population ratio method as it is recommended for the assessment of intervention effects.[36] When multiple recalls are available, the population ratio method provides a less biased estimate of the mean HEI score than the simple scoring algorithm or mean ratio method.[137]

Briefly, the population ratio method calculates the means of dietary constituents across all individuals prior to constructing ratios and scoring. Bootstrap resampling was utilized to estimate 95% confidence intervals (CIs) for mean HEI 2015 scores for each treatment group for each study time point with 200 bootstrap resamples generated. To test the hypotheses, confidence intervals were compared for overlap. As recommended, radar plots were used to visualize component scores of the HEI-2015.[25]

4.3.2 Statistical Analysis

The distributions of continuous variables were assessed for normality using histograms and normal probability plots. For continuous-type normally distributed variables, comparison of baseline characteristics between those with complete data at all time points and those with missing data at 6 and/or 12 months was conducted using pooled variance t-tests when group variances were equal or with the Satterthwaite method when group variances were not equal. Wilcoxon rank-sum tests were applied to compare group-specific distributions when the distribution of continuous-type variables was not normal. Chi-square tests were used to compare distributions of categorical variables between those with and without missing dietary data. All analyses were performed using SAS version 9.4 [SAS Institute, Inc., Cary, NC, USA].

There was no observed difference in mean weight loss, the primary outcome of the study, between study arms at either 6- or 12-months;[266, 267] therefore, data for the groups were combined when assessing the diet quality over time of those achieving clinically meaningful weight loss (≥5% of baseline weight) at both 6 months and 12 months compared to those without clinically meaningful weight loss.

4.4 Results

Of the 502 participants enrolled (251 SM; 251 SM+FB), 356 were included in this secondary data analysis (Figure 7) as retention at 12 months was 78.5%[267] and because some participants retained in the study did not contribute dietary data. Demographic characteristics of the total sample and by missingness category are presented in Table 13. Participants in this complete case analyses were middle-aged (median=51.0 years) and had obesity (median BMI=33.1). The sample was mostly female (78.9%) and white (85.4%). As previously published, there were no statistically significant differences between SM and SM+FB groups at baseline.[266]

Participants with complete dietary data (N=356), defined as having ≥1 dietary recall at all timepoints, were significantly older ($p<0.0001$), more likely to identify as white ($p=0.01$), and more likely to report high blood pressure ($p<0.01$) and high cholesterol ($p<0.01$) at baseline compared to those who were missing dietary data at 6 and/or 12 months. Participants with complete data also had significantly lower BMI ($p=0.03$) and higher systolic blood pressure measured at baseline ($p=0.04$) compared to those with missing dietary data. The percent of participants with complete dietary data did not differ by treatment assignment (SM=67.7% vs. SM+FB=74.1%, chi-square p= 0.1159).

At baseline mean HEI-2015 total scores and bootstrapped 95% CIs were similar by treatment group (SM+FB: 63.11 [61.19-64.6]; SM: 61.02 [59.39-62.34]) (Table 14). For both groups, little improvement in HEI-2015 total scores from baseline were observed at 6 months (SM+FB: 65.42 [63.98-66.83]; SM: 63.32 [61.87-64.73]) or 12 months (SM+FB: 63.94 [62.04-65.75]; SM: 63.56 [61.48-64.98]). Similarly, changes in component scores were small between groups and across time points. Figure 8 depicts component scores at each time point by treatment group.

Among those at 6 months who lost ≥5% of baseline weight (n=130) compared to those who did not (<5%), mean HEI-2015 scores and bootstrapped CIs were greater at 6 months (67.46 [65.61-69.44] vs. 62.41 [60.96-63.42], respectively) (Table 15) despite similar HEI-2015 scores at baseline (62.18 [60.33-64.29] vs. 62.06 [60.39-63.24], respectively). However, by 12 months, mean HEI-2015 scores were similar by weight loss status (≥5% weight loss: 65.38 [63.51, 67.28] vs. <5% weight loss: 62.72 [61.04, 64.18]). Component scores are presented in Figure 9 for weight loss status at 6 months.

Results were similar when assessing weight loss status at 12 months (Table 16 and Figure 10). Again, at baseline, there were no differences in HEI-2015 total scores by 12-month weight loss status (≥5% weight loss: 62.00 [59.62-63.69] vs.<5% weight loss: 62.17 [60.67-63.21]). Among those at 12 months who lost ≥5% of baseline weight (n=125) compared to those who did not (<5%), mean HEI-2015 scores and bootstrapped CIs were greater at 6 months (68.02 [66.29-70.67] vs. 62.36 [60.82-63.53], respectively) and remained greater at 12 months (65.93 [64.00-67.91] vs. 62.50 [60.77-63.86], respectively).

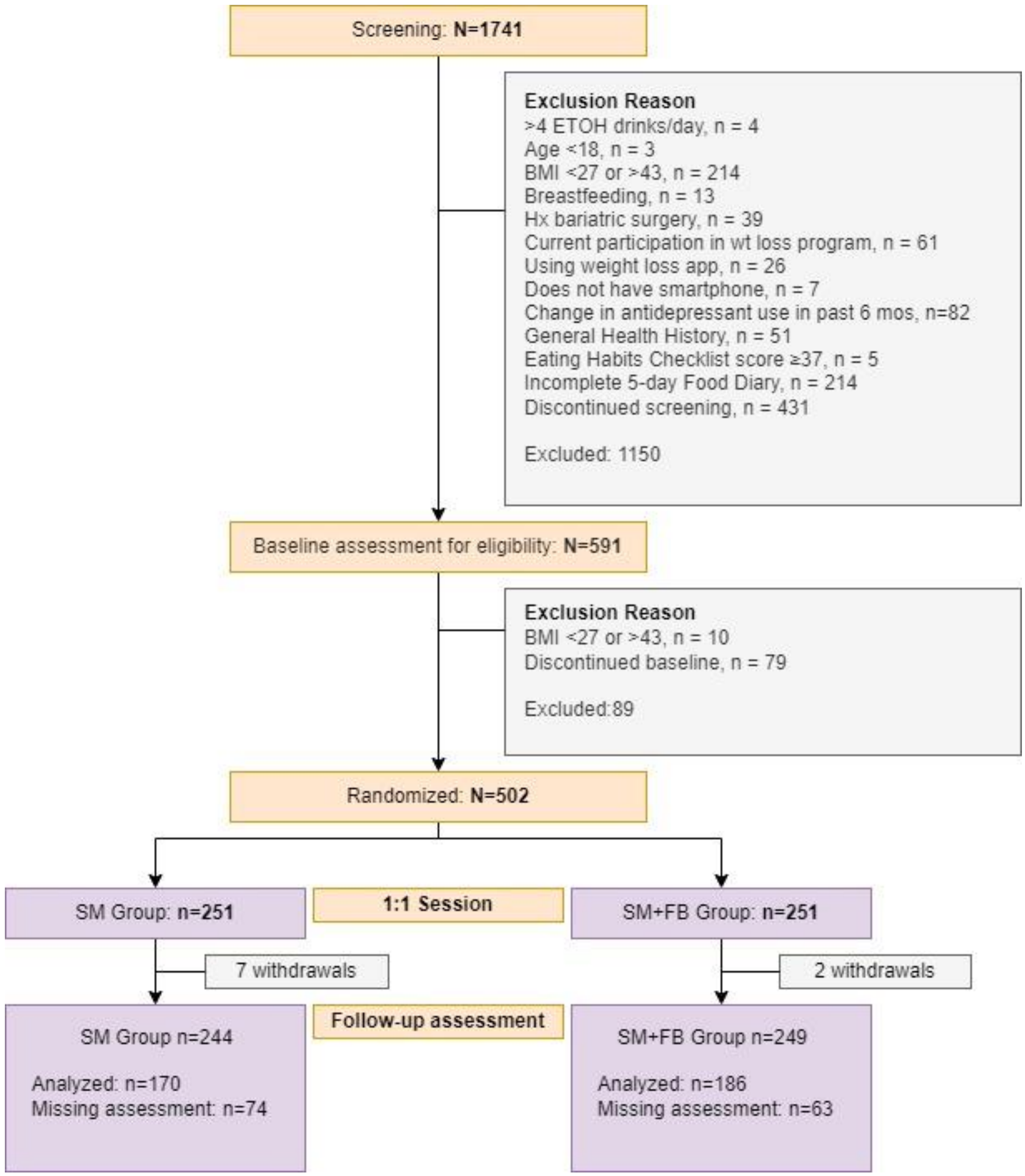


Figure 7: CONSORT (Consolidated Standards of Reporting Trials) flow diagram for SMARTER Study Participants Included in a Secondary Analysis of Diet Quality Outcomes

Notes: ETOH=ethyl alcohol; BMI=Body Mass Index; HX=history; FB, feedback; SM, self- monitoring.

Table 13: Baseline Characteristics of SMARTER Study Participants by Dietary Data Missingness Status

Characteristic	Total Sample N=502 Mean ± SD	Complete Dietary Data n=356 Mean ± SD	Missing Dietary Data† n=146 Mean ± SD	p-value
Demographic characteristics				
Age, y (median, p25, p75)	45.5 (32.0, 57.0)	51.0 (36.0, 60.0)	35.0 (29.0, 46.0)	<.0001*
Sex, n (%)				
Male	103 (20.5)	75 (21.1)	28 (19.2)	0.63
Female	399 (79.5)	281 (78.9)	118 (80.8)	
Race and Ethnicity, n (%)				
Asian	14 (2.8)	8 (2.3)	6 (4.1)	0.01*
Black	48 (9.6)	32 (9.0)	16 (11.0)	
Multiracial¥	26 (5.2)	12 (3.4)	14 (9.6)	
White	414 (82.5)	304 (85.4)	110 (75.3)	
Education, y	16.4 ± 2.8	16.5 ± 2.8	16.4 ± 2.9	0.72
Employment, n (%)				
Full-time / Part-time	412 (82.1)	291 (81.7)	121 (82.9)	0.76
Unemployed‡	90 (17.9)	65 (18.3)	25 (17.1)	
Annual household income, n (%)				
<$60,000	143 (28.5)	97 (30.0)	46 (34.6)	0.34
≥$60,000	313 (62.4)	226 (70.0)	87 (65.4)	
Clinical characteristics (self-reported)				
High blood pressure, n (%)	106 (21.1)	87 (24.4)	19 (13.0)	<0.01*
High cholesterol, n (%)	88 (17.5)	74 (20.8)	14 (9.6)	<0.01*
High triglycerides, n (%)	56 (11.2)	44 (12.4)	12 (8.2)	0.18
Smoking status, n (%)				
Never smoker	385 (76.7)	273 (76.7)	112 (76.7)	0.48
Current smoker	14 (2.8)	8 (2.3)	6 (4.1)	
Former smoker	103 (20.5)	75 (21.1)	28 (19.2)	
Anthropometric measures				
Body mass index, kg/m^2 (median, p25, p75)	33.3 (30.7, 36.6)	33.1 (30.3, 36.2)	33.8 (31.0, 37.5)	0.03*
Average waist circumference, cm				
Men	113.1 ± 12.2	112.5 ± 11.9	114.7 ± 13.0	0.43
Women	105.3 ±11.1	105.5 ± 10.5	104.9 ± 12.4	0.62
Average systolic blood pressure, mmHg	118.2 ± 15.4	119.1 ± 15.1	116.0 ±16.0	0.04*
Average diastolic blood pressure, mmHg	77.0 ± 10.8	76.9 ± 10.8	77.0 ± 10.9	0.97

†Dietary data were missing at 6- and/or 12-months if there were 0 recalls collected at that timepoint.
‡The Unemployed category includes participants who were unemployed, retired, or disabled.
*Statistically significant at the p<0.05 level
¥Indicates participants self-reported “yes” to a question, “Are you of more than one racial/ethnic background?”
Notes: For categorical variables, p-values were obtained using the chi-square test of independence. For age, BMI, and body fat percentage the Wilcoxon rank-sum test was used to assess differences by missingness category because of non-normality identified during visualization of histograms and q-q plots. Two-sided p-values are presented. For all other continuous variables, two sample t-tests were used to assess differences by missingness category as plots suggested normality. For all continuous variables except female waist circumference, the pooled variance method was used as variances were equal. The Satterthwaite method was used for female waist circumference.

Table 14: Healthy Eating Index (HEI-2015) Total and Component Scores by Treatment Group and Time Point

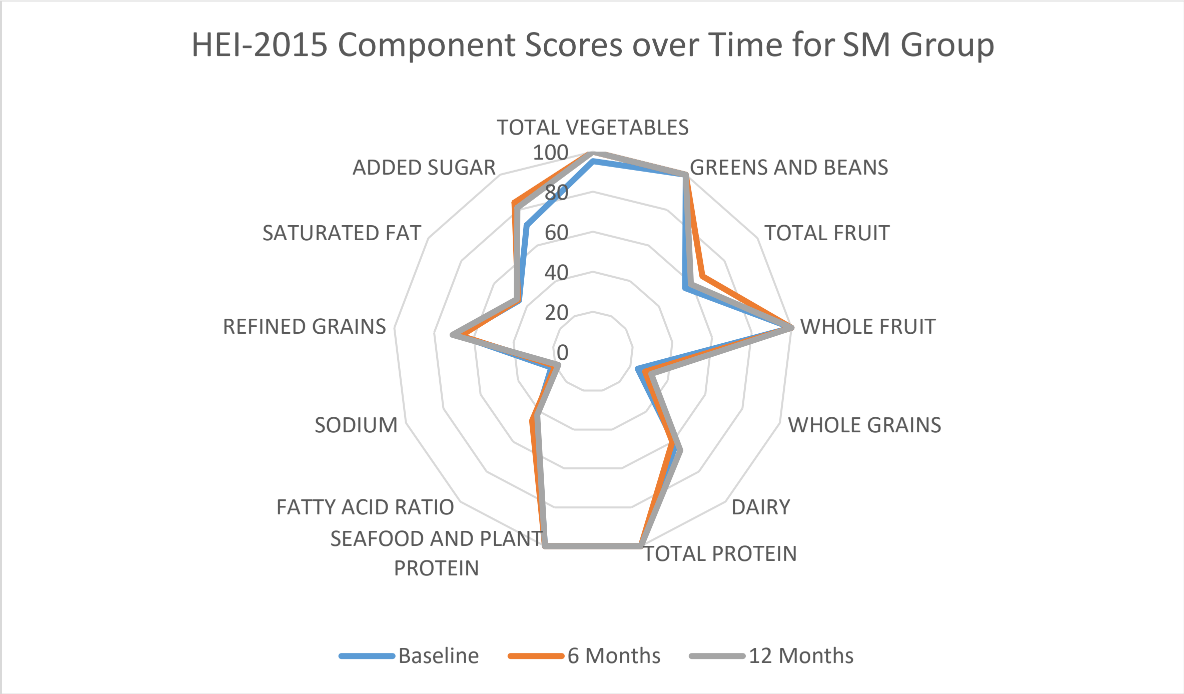
	Study Arm	Baseline Mean [95% CI]	6 Months Mean [95% CI]	12 Months Mean [95% CI]
TOTAL HEI-2015 SCORE	SM	61.02 [59.39-62.34]	63.32 [61.87-64.73]	63.56 [61.48-64.98]
	SM+FB	63.11 [61.19-64.6]	65.42 [63.98-66.83]	63.94 [62.04-65.75]
Adequacy Components				
TOTAL VEGETABLES	SM	4.76 [4.44-5.00]	5.00 [4.63-5.00]	5.00 [4.86-5.00]
	SM+FB	4.71 [4.44-5.00]	5.00 [4.92-5.00]	4.78 [4.47-5.00]
GREENS AND BEANS	SM	5.00 [5.00-5.00]	5.00 [5.00-5.00]	5.00 [5.00-5.00]
	SM+FB	5.00 [5.00-5.00]	5.00 [5.00-5.00]	5.00 [5.00-5.00]
TOTAL FRUIT	SM	2.80 [2.47-3.11]	3.32 [2.95-3.72]	2.97 [2.57-3.31]
	SM+FB	2.81 [2.44-3.16]	3.17 [2.84-3.56]	3.01 [2.67-3.34]
WHOLE FRUIT	SM	5.00 [4.43-5.00]	5.00 [5.00-5.00]	5.00 [4.53-5.00]
	SM+FB	5.00 [4.47-5.00]	5.00 [4.92-5.00]	5.00 [4.85-5.00]
WHOLE GRAINS	SM	2.39 [2.08-2.74]	2.79 [2.46-3.20]	3.12 [2.70-3.52]
	SM+FB	2.93 [2.48-3.26]	3.57 [3.1-3.94]	3.55 [3.06-4.01]
DAIRY	SM	6.22 [5.82-6.62]	5.99 [5.53-6.44]	6.58 [6.13-7.01]
	SM+FB	6.57 [6.16-6.96]	6.08 [5.60-6.50]	5.89 [5.47-6.25]
TOTAL PROTEIN FOODS	SM	5.00 [5.00-5.00]	5.00 [5.00-5.00]	5.00 [5.00-5.00]
	SM+FB	5.00 [5.00-5.00]	5.00 [5.00-5.00]	5.00 [5.00-5.00]
SEAFOOD AND PLANT PROTEIN	SM	5.00 [5.00-5.00]	5.00 [5.00-5.00]	5.00 [5.00-5.00]
	SM+FB	5.00 [5.00-5.00]	5.00 [5.00-5.00]	5.00 [5.00-5.00]
Moderation Components				
FATTY ACID RATIO	SM	4.26 [3.75-4.73]	4.59 [4.10-5.08]	4.20 [3.73-4.70]
	SM+FB	4.76 [4.22-5.20]	4.97 [4.49-5.40]	5.07 [4.60-5.54]
SODIUM	SM	2.22 [1.74-2.88]	1.99 [1.43-2.58]	1.85 [1.25-2.42]
	SM+FB	2.21 [1.71-2.65]	1.59 [1.00-2.11]	1.46 [0.78-2.03]
REFINED GRAINS	SM	6.74 [6.22,7.27]	6.65 [6.07-7.10]	7.07 [6.57-7.58]

	SM+FB	6.6 [6.01-7.15]	7.12 [6.7-7.66]	6.48 [5.92-6.93]
	SM	4.50 [3.94-4.94]	4.56 [4.03-5.05]	4.63 [4.11-5.17]
SATURATED FAT	SM+FB	4.39 [3.96-4.85]	5.53 [5.10-5.95]	5.17 [4.73-5.68]
	SM	7.14 [6.68-7.58]	8.42 [8.05-8.77]	8.14 [7.75-8.61]
ADDED SUGAR	SM+FB	8.15 [7.84-8.44]	8.39 [8.08-8.70]	8.54 [8.23-8.80]
Note: 95% CI are based on bootstrapped resamples				

Table 15: HEI-2015 Scores at Each Time Point by Weight Loss Status at 6 Months

	Weight Loss Status at 6 Months	Baseline Mean [95% CI]	6 Months Mean [95% CI]	12 Months Mean [95% CI]
TOTAL HEI-2015 SCORE	<5%	62.06 [60.39-63.24]	62.41 [60.96, 63.42]	62.72 [61.04, 64.18]
	≥5%	62.18 [60.33-64.29]	67.46 [65.61, 69.44]	65.38 [63.51, 67.28]
Adequacy Components				
TOTAL VEGETABLES	<5%	4.74 [4.44-5.00]	4.66 [4.33-4.93]	4.68 [4.41-5.00]
	≥5%	4.73 [4.39-5.00]	5.00 [5.00-5.00]	5.00 [5.00-5.00]
GREENS AND BEANS	<5%	5.00 [5.00-5.00]	5.00 [5.00-5.00]	5.00 [5.00-5.00]
	≥5%	5.00 [5.00-5.00]	5.00 [5.00-5.00]	5.00 [5.00-5.00]
TOTAL FRUIT	<5%	2.76 [2.42-3.03]	2.8 [2.54-3.06]	2.9 [2.61-3.15]
	≥5%	2.89 [2.53-3.23]	4.15 [3.71-4.6]	3.16 [2.72-3.52]
WHOLE FRUIT	<5%	5.00 [4.42-5.00]	5.00 [4.48-5.00]	5.00 [4.54-5.00]
	≥5%	5.00 [4.63-5.00]	5.00 [5.00-5.00]	5.00 [5.00-5.00]
WHOLE GRAINS	<5%	2.56 [2.27-2.81]	2.85 [2.55-3.17]	3.16 [2.83-3.5.0]
	≥5%	2.85 [2.31-3.29]	3.87 [3.39-4.42]	3.69 [3.17-4.34]
DAIRY	<5%	6.45 [6.16-6.79]	6.03 [5.60-6.46]	6.11 [5.75-6.44]
	≥5%	6.3.0 [5.80-6.80]	6.11 [5.70-6.58]	6.39 [5.83-6.82]
TOTAL PROTEIN FOODS	<5%	5.00 [5.00-5.00]	5.00 [5.00-5.00]	5.00 [5.00-5.00]
	≥5%	5.00 [5.00-5.00]	5.00 [5.00-5.00]	5.00 [5.00-5.00]
SEAFOOD AND PLANT PROTEIN	<5%	5.00 [5.00-5.00]	5.00 [5.00-5.00]	5.00 [5.00-5.00]
	≥5%	5.00 [5.00-5.00]	5.00 [5.00-5.00]	5.00 [5.00-5.00]
FATTY ACID RATIO	<5%	4.44 [3.98-4.85]	4.56 [4.21-5.00]	4.52 [4.17-4.93]
	≥5%	4.66 [4.11-5.32]	5.10 [4.46-5.76]	4.89 [4.39-5.60]
Moderation Components				
SODIUM	<5%	2.47 [2.00-2.89]	1.92 [1.39-2.37]	1.82 [1.32-2.26]
	≥5%	1.78 [1.11-2.48]	1.45 [0.64-2.02]	1.33 [0.62-1.98]
REFINED GRAINS	<5%	6.55 [6.06-6.99]	6.45 [6.05-6.89]	6.44 [5.98-6.90]

	≥5%	6.86 [6.24-7.47]	7.69 [7.00-8.43]	7.32 [6.81-8.03]
SATURATED FAT	<5%	4.43 [4.05-4.84]	4.84 [4.43-5.26]	4.76 [4.32-5.18]
	≥5%	4.46 [3.91-5.03]	5.50 [4.99-6.08]	5.19 [4.62-5.80]
ADDED SUGAR	<5%	7.67 [7.30-8.1]	8.29 [8.00-8.57]	8.32 [8.00-8.61]
	≥5%	7.65 [7.21-8.24]	8.59 [8.29-8.93]	8.4 [7.93-8.77]
Note: 95% CI are based on bootstrapped resamples				



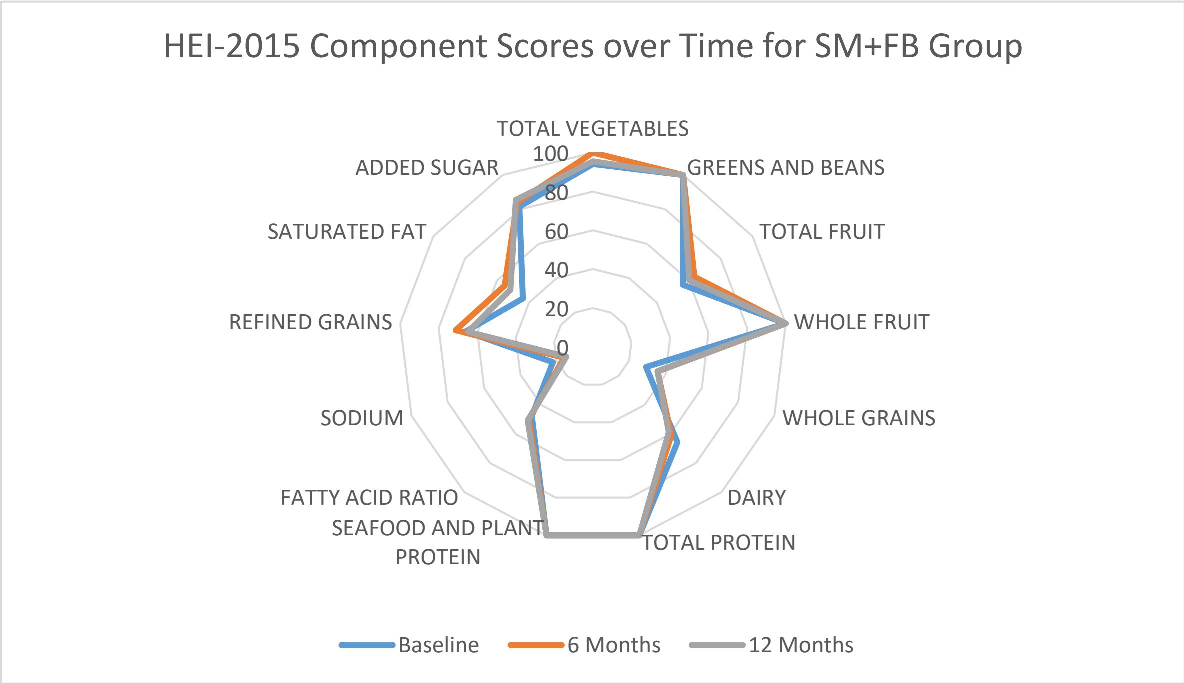
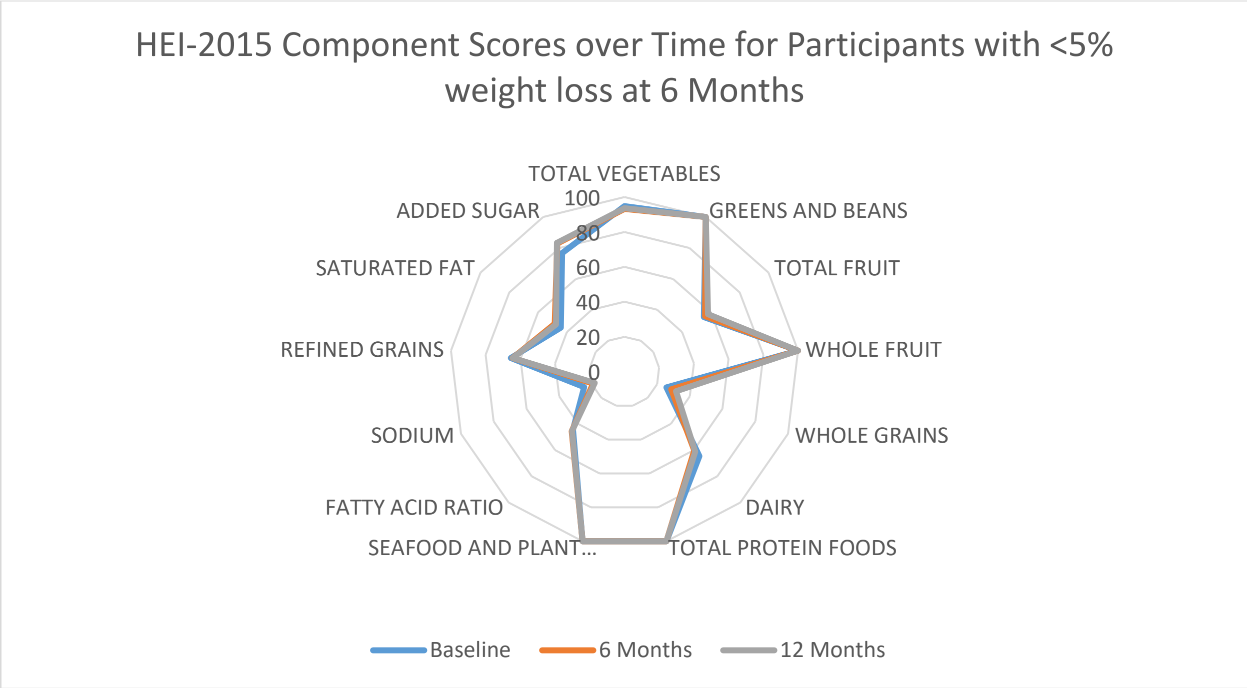


Figure 8: Radar Plot Depicting Component Scores of the Healthy Eating Index 2015 by Group at Each Time Point

Note: Scores touching the outer ring represent the maximum score for a component (100% of the maximum score). A perfect diet quality score of 100 would be represented by touching the outer ring for all components.



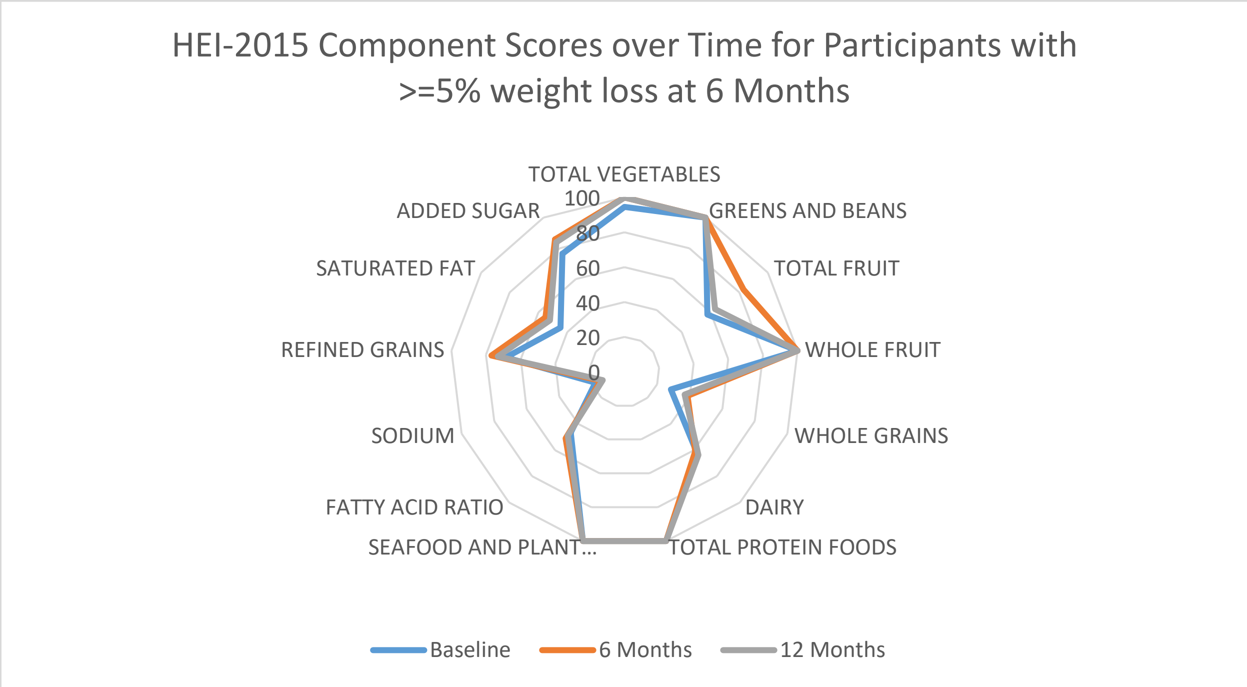


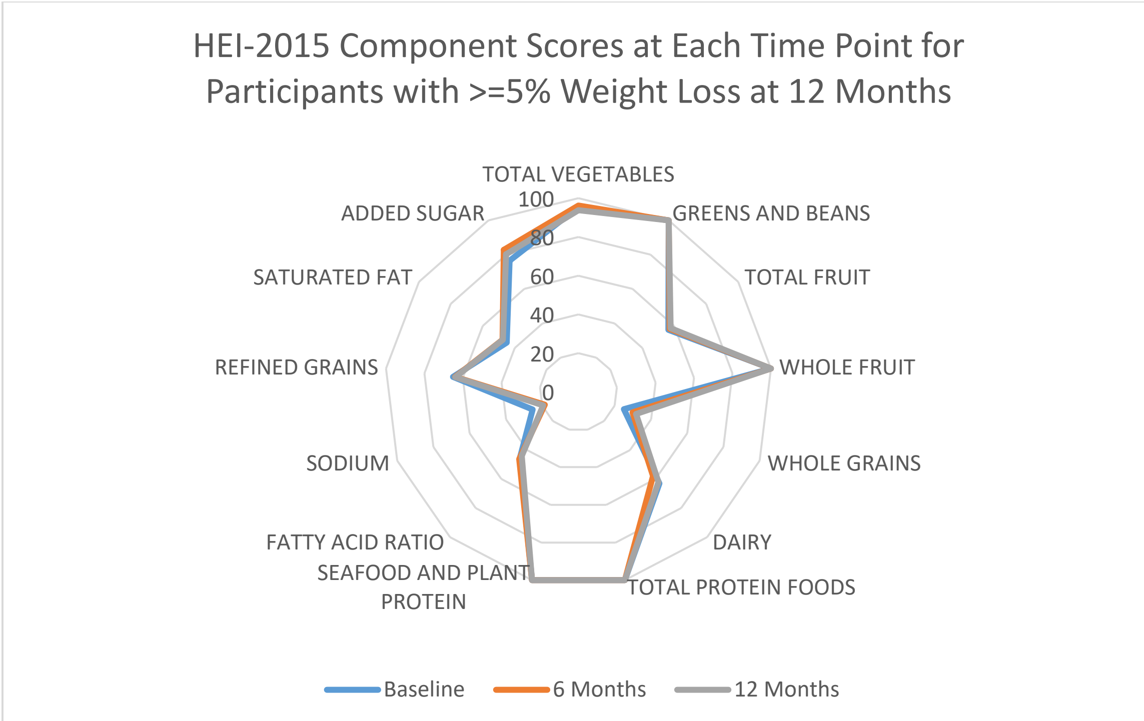
Figure 9: Radar Plot Depicting Component Scores of the Healthy Eating Index 2015 by 6-Month Weight Loss Status at Each Time Point

Note: Scores touching the outer ring represent the maximum score for a component (100% of the maximum score). A perfect diet quality score of 100 would be represented by touching the outer ring for all components.

Table 16: HEI-2015 Scores at Each Time Point by Weight Loss Status at 12 Months

	Weight Loss Status at 12 Months	Baseline Mean [95% CI]	6 Months Mean [95% CI]	12 Months Mean [95% CI]
TOTAL HEI-2015 SCORE	<5%	62.17 [60.67-63.21]	62.36 [60.82-63.53]	62.50 [60.77-63.86]
	≥5%	62.00 [59.62-63.69]	68.02 [66.29-70.67]	65.93 [64.00-67.91]
Adequacy Components				
TOTAL VEGETABLES	<5%	4.77 [4.48-5.00]	4.81 [4.53-5.00]	4.69 [4.41-4.98]
	≥5%	4.67 [4.29-5.00]	5.00 [5.00-5.00]	5.00 [5.00-5.00]
GREENS AND BEANS	<5%	5.00 [5.00-5.00]	5.00 [5.00-5.00]	5.00 [5.00-5.00]
	≥5%	5.00 [5.00-5.00]	5.00 [5.00-5.00]	5.00 [5.00-5.00]
TOTAL FRUIT	<5%	2.82 [2.50-3.10]	2.86 [2.61-3.15]	2.89 [2.61-3.17]
	≥5%	2.77 [2.41-3.12]	4.08 [3.61-4.68]	3.19 [2.65-3.63]
WHOLE FRUIT	<5%	5.00 [4.59-5.00]	5.00 [4.57-5.00]	5.00 [4.54-5.00]
	≥5%	5.00 [4.41-5.00]	5.00 [5.00-5.00]	5.00 [4.91-5.00]
WHOLE GRAINS	<5%	2.51 [2.25-2.81]	2.98 [2.59-3.29]	3.18 [2.89-3.51]
	≥5%	2.96 [2.53-3.48]	3.64 [3.18-4.04]	3.67 [3.01-4.23]
DAIRY	<5%	6.30 [5.97-6.64]	5.79 [5.44-6.12]	6.22 [5.88-6.63]
	≥5%	6.58 [6.04-7.13]	6.6 [6.11-7.11]	6.19 [5.72-6.60]
TOTAL PROTEIN FOODS	<5%	5.00 [5.00-5.00]	5.00 [5.00-5.00]	5.00 [5.00-5.00]
	≥5%	5.00 [5.00-5.00]	5.00 [5.00-5.00]	5.00 [5.00-5.00]
SEAFOOD AND PLANT PROTEIN	<5%	5.00 [5.00-5.00]	5.00 [5.00-5.00]	5.00 [5.00-5.00]
	≥5%	5.00 [5.00-5.00]	5.00 [5.00-5.00]	5.00 [5.00-5.00]
FATTY ACID RATIO	<5%	4.57 [4.11-5.10]	4.62 [4.22-4.99]	4.41 [3.99-4.9]
	≥5%	4.42 [3.82-5.07]	4.99 [4.32-5.71]	5.13 [4.69-5.67]
Moderation Components				
SODIUM	<5%	2.53 [2.12-2.92]	1.86 [1.38-2.40]	1.95 [1.47-2.43]
	≥5%	1.64 [0.94-2.34]	1.56 [0.93-2.40]	1.06 [0.32-1.81]
REFINED GRAINS	<5%	6.52 [5.99-6.87]	6.41 [6.04-6.88]	6.4 [5.87-6.85]
	≥5%	6.93	7.81	7.45

		[6.12-7.48]	[6.96-8.49]	[6.87-8.08]
SATURATED FAT	<5%	4.49 [4.08-4.90]	4.75 [4.33-5.13]	4.73 [4.25-5.16]
	≥5%	4.35 [3.71-4.96]	5.73 [5.17-6.40]	5.28 [4.61-5.90]
ADDED SUGAR	<5%	7.65 [7.27-8.05]	8.28 [8.01-8.63]	8.03 [7.7-8.36]
	≥5%	7.67 [7.25-8.11]	8.62 [8.3-9.01]	8.96 [8.61-9.34]
Note: 95% CI are based on bootstrapped resamples				



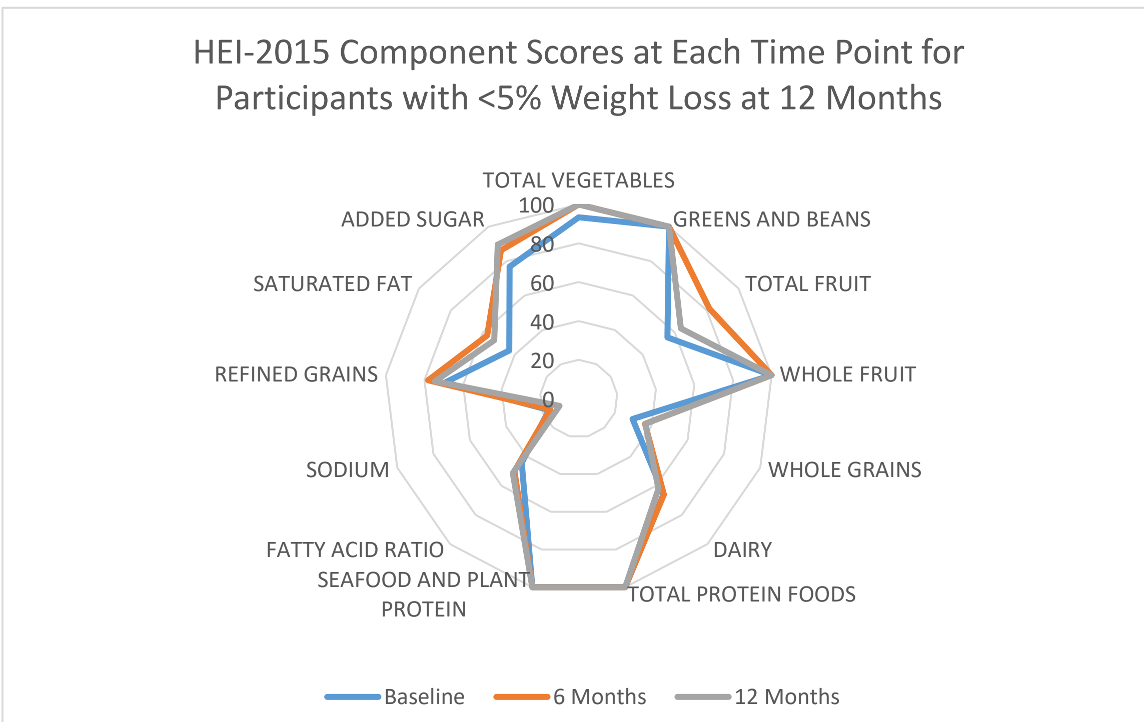


Figure 10: Radar Plot Depicting Component Scores of the Healthy Eating Index 2015 by 12-Month Weight Loss Status at Each Time Point

Note: Scores touching the outer ring represent the maximum score for a component (100% of the maximum score). A perfect diet quality score of 100 would be represented by touching the outer ring for all components.

4.5 Discussion

Little change in HEI-2015 scores were observed over 12 months in either the SM or SM+FB group. Our results are similar in magnitude to those reported in other remote interventions. For example, small improvements in diet quality (~2 points) have been observed at 6- and 12-month time points in the cellphone-based arm of a behavioral intervention despite specific emphasis on following the Dietary Approaches to Stop Hypertension (DASH) eating pattern.[238] In a workplace intervention that included automated feedback, 6-, 12-, and 24-month improvements in HEI-2015 scores were similarly small (2.2, 1.8, and 1.6 points respectively).[268] Additionally, in an internet-based weight loss intervention with energy and fat goals, self-monitoring, and automated feedback, diet quality improved by approximately 4 points over 3 months.[241] However, as diet quality improvements have been seen to lessen over the course of an intervention,[208, 230] additional follow-up time might have shown attenuated results.

Limited engagement with digital self-monitoring might have precluded improvement in diet quality in our study. Dietary self-monitoring declined curvilinearly over time with only about half of days being self-monitored over 12 months on average,[269] and the median percentage of feedback messages intervention participants viewed over the 12 months was 42.19%.[267] Such issues with engagement might underly the lack of differences over time as well as the lack of differences between groups since the number of diet-related feedback messages a participant receives is related to weight loss only indirectly through self-monitoring adherence.[270]

The single session with a dietician at baseline in SMARTER may not have been sufficient for inducing diet quality change, and there were no specific goals for altering macronutrient intake, other than fat intake. Many behavioral weight loss programs such as ours, draw from the Diabetes Prevention Program (DPP). However, diet quality improvements in the DPP were small despite a high level of coach contact. The authors suggest this may be because only one intervention session directly addressed healthy eating independent of weight loss.[201, 271] Indeed, it may be that improvements in diet quality were small because there was no explicit focus on altering components of diet quality identified in by the HEI. In a study in which sessions were specifically focused on recommendations from the DGA, the number of sessions attended was positively associated with HEI-2005 scores.[208]

Despite the lack of a significant difference between SM+FB and SM groups, the 5-6 point improvement from baseline that we observed among participants with clinically meaningful weight loss at 6 months was similar to what has been suggested as a likely meaningful difference between groups.[36] Our results were similar when assessing weight loss status at 12 months as 76.0% of those who lost ≥5% of baseline weight at 12 months had already lost 5% of baseline weight by the 6 month time point.

While it is important to note a clinically meaningful cut point for improvement in diet quality has not been established and scores from different versions of the HEI (and different indices) are not directly comparable, the relationship we observed between weight loss and HEI improvement is broadly similar to that seen in other studies. In a small pilot study with a 16-week intervention period, women who achieved clinically meaningful weight loss improved HEI-2005 total score by 8.3 points.[207] In both the Weight Optimization Revamping Lifestyle using the Dietary Guidelines (WORLD)[208] and Daughters and Mothers Against Breast Cancer (DAMES)[209] studies, which used the HEI-2005, relationships between change in diet quality and weight loss were also observed. Additionally, among rural breast cancer survivors who maintained lost weight (≥5% of baseline weight) versus those who did not, there was a 4.6-point difference in Alternate Healthy Eating Index (AHEI) scores at 18 months.[205] Such accumulating evidence of a relationship between diet quality and weight loss reinforces the need for thorough consideration of diet quality in intervention design and analysis.

4.5.1 Strength and Limitations

A scoping review of mobile-based interventions concluded there was inadequate examination of dietary behavior change and its relationship to health outcomes.[272] A major strength of this study is that it is one of the few to explore this question rigorously by using multiple 24-hr dietary recalls, which are less biased than food frequency questionnaires, and appropriate calculation of the Healthy Eating Index. Additional strengths of the study include the randomized design, relatively large sample size, and the intervention's scalability.

However, reporting error cannot be ruled out as recalls were not unannounced, thus reducing one of the main advantages of using dietary recalls.[112] Similarly, a little less than half of participants had both a weekday and weekend dietary recall at baseline with less than a third contributing both a weekday and weekend recall at 6 and 12 months. Most participants contributed two non-consecutive recalls at baseline with only about half doing so at 6 months and 12 months. Collecting data on both weekdays/weekends and on non-consecutive days may reduce error as weekday eating has been shown to differ from weekend eating,[124] and consecutive days of recall tend to be more correlated.[123] A final limitation is that, our analysis included only those participants with complete data. Likely those with missing data had little to no improvement in diet quality due to their disengagement with the study. Therefore, had they been included, results might have been attenuated.

4.5.2 Future Directions

In conclusion, minimal diet quality improvement was observed in this mHealth intervention among participants with overweight and obesity. When there is excessive energy intake, as with those with overweight/obesity, a focus on addressing low scores for refined grains, added sugars, and/or saturated fats might be most beneficial to improving diet quality scores for two reasons. First, the general population has particularly low scores on these components. Second, as described by Krebs-Smith and colleagues, focus on these components would lead to improvements in all components scores that are density-based because refined grains, added sugars, and saturated fats contribute a large number of calories.[25] In SMARTER, no messages addressed sodium and few addressed grains (refined or whole) or saturated fat specifically. Therefore, more focused feedback messages might help induce changes in diet quality.

Personalization of features besides feedback, such as delivery or timing,[273] increasing self-efficacy, and culturally-tailoring nutritional feedback have also been suggested as ways of increasing the benefits of remote, personalized interventions.[194] However, because diet quality improvement in weight loss trials has not been extensively explored, components of interventions necessary for producing diet quality improvement remain unclear. As such, weight loss researchers may consider assessing improvements in diet quality such that clarity can be achieved. Widening focus when designing interventions to include improvement not only for weight and other cardiometabolic outcomes, but also for health behaviors such as diet quality, may benefit participants having difficulty achieving or maintaining weight loss.

5.0 Manuscript 3: Perceived and Measured Diet Quality Improvements in a Randomized Weight Loss Trial

5.1 Abstract

Background: The diet quality of US adults is generally poor and cross-sectional analyses suggest self-perception of healthful dietary intake may be overestimated.

Purpose: This analysis assessed the concordance between calculated and perceived diet quality and improvements in diet quality among weight-loss seeking adults enrolled in a 12-month randomized behavioral trial.

Methods: Healthy Eating Index-2015 diet quality was calculated from self-administered 24-hour recalls. Perceived diet quality was measured on a 100-point scale. Concordance was assessed using the concordance correlation coefficient and Bland-Altman plots.

Results: Participants with complete dietary data (n=105) were mostly female (80%), and white (86.7%). There was good agreement between HEI and PDQ scores at 12 months for 27.6% of participants. Most of the disagreement arose from PDQ scores (median [p25, p75]: 71.0 [60.0, 82.0]) being higher than HEI scores (median [p25, p75]: 56.06 [46.76, 67.13]). Only 13.3% of participants had good agreement between change in HEI and change in PDQ scores. Participants perceived greater improvement in diet quality (median [p25, p75]: 20.0 [8, 30]) than indicated by HEI scores (median [p25, p75]: 1.38 [-7.74, 11.76]). Concordance was low [concordance correlation coefficient (95% confidence interval)] at 12 months [0.40 (0.29, 0.49)] and for change in diet quality [0.19 (0.07, 0.30)].

Conclusion: Despite the diet quality of weight loss-seeking adults being less than ideal and with little evidence of improvement, many perceived their diet quality and improvements in diet quality as better than measured. Future studies might explore the effect of misperceptions on weight loss outcomes.

5.2 Introduction

The theory of planned behavior posits that beliefs precede attitudes, subjective norms, and perceived behavioral control which in turn influence change intentions and resultant behavior.[274, 275] Applied to dietary modification, dietary beliefs and perception of diet influences intention to alter diet[276] as well as diet-related behaviors.[277] Previous research in the general population has shown a tendency for people to overestimate their diet quality[278, 279] as well as overestimate intake of 'healthful' components of diet such as fruits and vegetables.[280] Therefore, it is important to assess the perceived diet quality (PDQ) of those attempting to alter their diet both prior to altering the diet and after making changes.

Diet quality represents the healthfulness of one's overall diet and has been linked to cardiometabolic risk factors and disease.[153, 156, 170] The Healthy Eating Index (HEI) is a valid and reliable measure of diet quality corresponding to the Dietary Guidelines for Americans. The HEI-2015 includes nine adequacy (e.g., greens and beans) and four moderation components (e.g., added sugar).[25, 37, 38]

In the US adult population, two major analyses have assessed the cross-sectional relationship between objectively measured diet quality and PDQ using a single item (i.e., "In general, how healthy is your overall diet?") with five response options ranging from 'poor' to ‘excellent’. Using data from the 2005-2006 National Health and Nutrition Examination Survey (NHANES), researchers found that despite a positive relationship between PDQ and adherence to the nutrient-based Dietary Approaches to Stop Hypertension (DASH) diet, those reporting high PDQ did not meet DASH recommendations for adequate intake.[279] Combining data from NHANES 2011-2018, researchers again observed a relationship with an 8.9-point difference in HEI-2015 total scores between those self-rating their diet quality as “poor” versus “excellent”.[281]

Examining relationships between PDQ and measured diet quality in those with overweight/obesity in a weight loss intervention may inform intervention development and delivery. Thus, we 1) assessed the cross-sectional agreement between PDQ and HEI-2015 total score at 12 months and 2) examined the agreement between perceived change in diet quality and change in HEI-2015 total score.

5.3 Methods

This is a secondary data analysis of the SMARTER randomized controlled trial (RCT) which has been described elsewhere.[265] Main results of this mobile health study showed no difference between arms in weight loss outcomes at 6 or 12 months.[266, 267] As such, in this analysis, the SM and SM+FB groups were combined. Briefly, the SMARTER RCT randomized adults with overweight and obesity to either 1) an arm which self-monitored diet, physical activity, and weight (SM) or 2) an arm which self-monitored but also received real-time personalized feedback based on self-monitoring data (SM+FB). Feedback was delivered up to three times per day over the 12-month intervention period on a study-specific phone app. Prior to randomization, all participants met one-on-one with a registered dietitian to discuss caloric restriction, fat gram, physical activity, and weight loss goals. While there was no diet quality goal, inherent in feedback messages was advice to eat a more balanced diet. SMARTER was approved by the University of Pittsburgh Institutional Review Board, and informed consent was obtained.

5.3.1 Measurements

Participants were asked to complete two dietary recalls at both baseline and 12 months using the National Cancer Institute's Automated Self-Administered 24-hour recall system.[113] The Healthy Eating Index-2015 total score was calculated using the simple scoring algorithm.[36] HEI change was calculated as (HEI-2015 total score post-intervention – HEI-2015 total score pre-intervention).

Perceived diet quality questions were added to SMARTER after all participants had completed the baseline assessment. Therefore, participants' self-perception of their diet quality pre-intervention and post-intervention were both assessed at 12 months.

To orient participants to important aspects of diet, prior to answering PDQ questions, participants rated the quality of their intake of each of the components which make up the HEI-2015. Examples of each of the components were provided, for example, "Refined Grains (e.g., white bread, white rice, white flour)".

Participants were provided the following definition of diet quality: "Diet quality can be thought of as how balanced your diet is, that is, getting enough of some types of foods and eating others in moderation." Participants were then asked "On a scale of 0 to 100, please rate your OVERALL diet quality ONE YEAR AGO (at the beginning of the study)" and "On a scale of 0 to 100, please rate your OVERALL diet quality NOW (at the end of the study)" with 0 representing the “worst possible” and 100 being the “best possible” diet quality. By subtracting the estimates (PDQ post-intervention – PDQ pre-intervention), perceived change in diet quality was calculated.

5.3.2 Statistical Analysis

Using histograms and normal probability plots, continuous variables were assessed for normality. To compare baseline characteristics of those with and without perceived diet quality data, when continuous variables were normally distributed, pooled variance t-tests were used as variances were equal across groups. Wilcoxon ranked sum tests were used for when data were not normally distributed. Chi-square tests of independence and Fisher’s Exact tests were used to compare distributions of categorical variables.

Concordance correlation coefficients[282] and Bland-Altman plots were used to assess the agreement between PDQ and HEI-2015 total score at 12 months as well as change in PDQ and change in HEI-2015 total score from pre-intervention to post-intervention (i.e., the 12 month timepoint). Bland-Altman plots are useful for evaluating bias and estimating an agreement interval.[283-285] Agreement between scores was set at 6 points as it has been suggested that a 5-6 point difference in HEI-2015 total scores between groups is likely meaningful.[36] Analyses were performed using SAS version 9.4 [SAS Institute, Inc., Cary, NC, USA] with the rm_ccc macro was used to calculate the concordance correlation coefficient.[286]

5.4 Results

About 2/3 of the 179 participants asked about perceived diet quality responded (with higher response rates after the questions were integrated into an existing survey). From the 502 participants enrolled, the analytic sample included 105 participants with both complete ASA-24 dietary recall at baseline and 12 months and complete PDQ data. Participants were mostly female (80%), white (86.7%), and with obesity (median BMI: 33.2 [p25, p75]: [30.7, 37.0]). Participants with complete data were significantly older than those without PDQ and ASA-24 data (median [p25, p75] years: 52.0 [37, 59] vs. 43 [31, 56], p=0.01); no other statistically significant differences were observed between the subsamples (Table 17).

For assessment of diet quality at 12 months, the concordance correlation coefficient and 95% confidence interval was 0.40 (0.29, 0.49). For the assessment of change in diet quality pre-intervention to post-intervention, the concordance correlation coefficient between HEI-2015 total score and PDQ was 0.19 (0.07, 0.30).

Differences between HEI-2015 total score and PDQ scores at 12 months ranged from -44.8 to 29.9 points (Figure 11), with a negative value indicating that the PDQ score was greater than the HEI-2015 total score. Bland-Altman plots suggested good agreement between HEI-2015 and PDQ scores for only 27.6% (29/105) of participants. At lower diet quality levels, participants perceived their diet quality to be worse than HEI-2015 total scores indicated; however, most of the disagreement between scores arose from PDQ scores (median [p25, p75]: 71.0 [60.0, 82.0]) being higher than HEI-2015 total scores (median [p25, p75]: 56.06 [46.76, 67.13]).

Figure 12 displays the Bland-Altman plot for the relationship between change in PDQ and change in HEI-2015 total scores from pre- to post-intervention. Only 13.3% (14/105) of participants had good agreement between change in HEI-2015 total scores and change in PDQ scores. Overall, differences between scores ranged from -68.4 to 39.6 points. Again, disagreement mainly arose from higher perceived improvement in diet quality (median [p25, p75]: 20.0 [8, 30]) compared to improvement in HEI-2015 total scores (median [p25, p75]: 1.38 [-7.74, 11.76]).

Table 17: Comparison of Baseline Characteristics of Participants with and without Complete Perceived Diet Quality Data

		Complete PDQ Data (n=105)	Missing PDQ Data (n= 397)	p-value
Treatment Assignment (SM+FB), n (%)		57 (54.3%)	194 (48.9%)	0.32
Age, y (median, p25, p75)		52 (37,59)	43 (31, 56)	0.01
Sex, n (%)	**Male**	21 (20%)	82 (20.7%)	0.88
	Female	84 (80%)	315 (79.3%)	
Race and Ethnicity, n (%)	**Asian**	0 (0.0%)	14 (3.5%)	0.22
	Black	9 (8.6%)	39 (9.8%)	
	More than One Race¥	5 (1.0%)	21 (5.3%)	
	White	91 (86.7%)	323 (81.4%)	
Annual household income, n (%)	**<$60k**	30 (30.6%)	113 (31.6%)	0.86
	≥$60k	68 (69.4%)	245 (68.4%)	
High cholesterol, n (%)		19 (18.1%)	69 (17.4%)	0.86
High triglycerides, n (%)		13 (12.4%)	43 (10.8%)	0.65
Body mass index, kg/m^2 (median, p25, p75)		33.2 (30.7, 37.0)	33.3 (30.7, 36.5)	0.88
Average waist circumference, cm, (mean ± SD)	**Men**	113.6 (13.6)	113.0 (11.9)	0.85
	Women	106.6 (12.3)	105.0 (10.8)	0.24
Average systolic blood pressure, mmHg (mean ± SD)		118.8 ± 14.6	118.0 ± 15.6	0.65
Average diastolic blood pressure, mmHg (mean ± SD)		78.1 ± 10.7	76.6 ± 10.8	0.20

Notes: cm=centimeters, PDQ=perceived diet quality, SD=standard deviation, SM+FB=Self-Monitoring and Feedback intervention group; kg/m^2=kilograms/meters squared, mmHg=milligrams of Mercury
†Dietary data was missing at 6- and/or 12-months if there were 0 recalls collected at that timepoint.
*Statistically significant at the p<0.05 level
¥Indicates participants who self-reported "yes" to a question, "Are you of more than one racial/ethnic background?"
Two-sided p-values are presented.

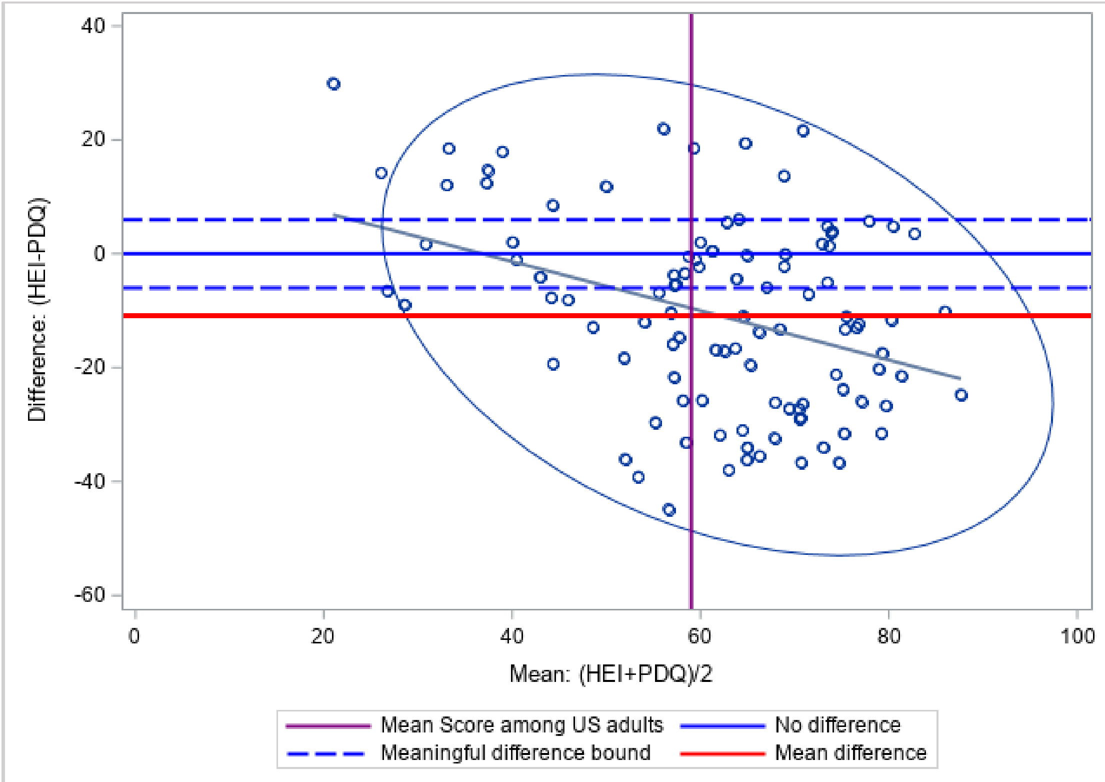


Figure 11: Bland-Altman Plot of the Difference (HEI-PDQ) vs. Mean at 12 Months

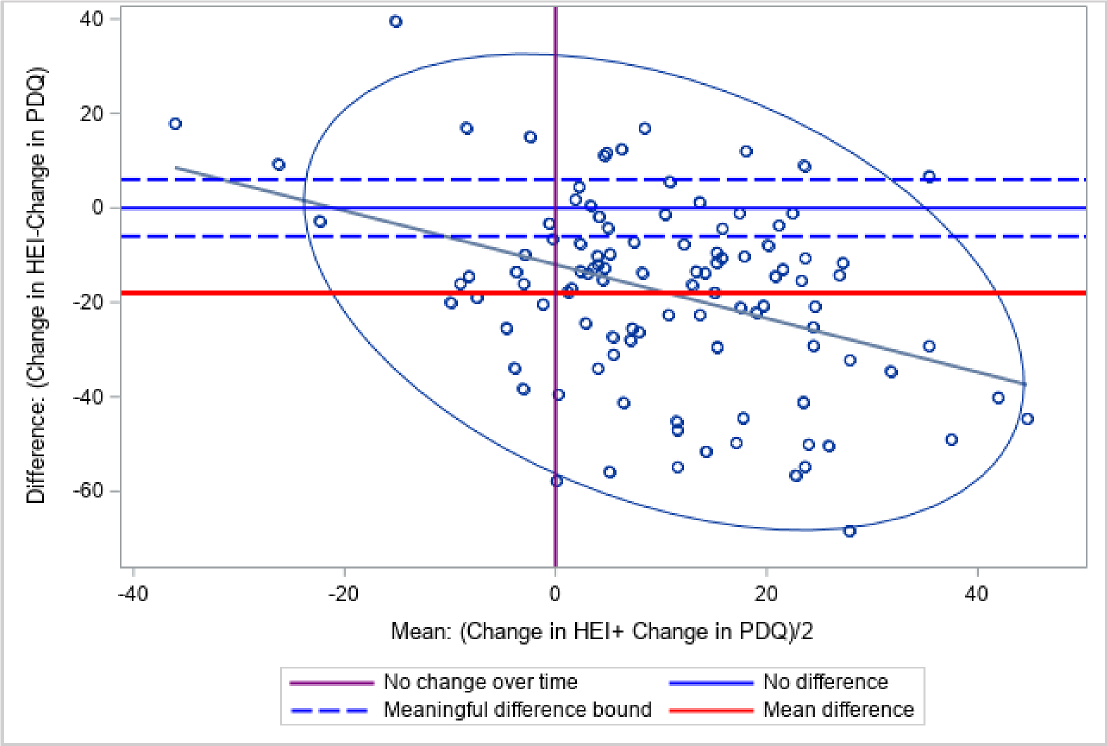


Figure 12: Bland-Altman Plot of the Difference (Change in HEI-Change in PDQ) vs. Mean Change from Pre-Intervention to Post-Intervention

5.5 Discussion

Results of this analysis suggest that weight loss seeking adults with overweight and obesity may be overly optimistic about their current diet quality as well as the improvements they have made in diet quality over the course of a behavioral weight loss intervention.

Implications for weight loss interventions are unclear as more optimistic perceptions of diet quality could conceivably benefit or harm participants' willingness and/or ability to make changes. Overestimation may lead to a belief that it is not important, or not very important, for an individual to alter their dietary habits. Indeed, in one study, perceived fat consumption was more significantly related to intention to reduce fat intake than objectively measured fat consumption.[276]

Alternately, participants who think positively about their current dietary habits and improvements may be more confident in their ability to make further improvements. For example, individuals whose subjective rating of their fruit and vegetable consumption was high had more positive beliefs about fruit and vegetables, reported more positive social influence to eat them, and had higher self-efficacy.[280]

The disconnect between perceived and measured diet quality may be bridged through medical nutrition therapy, more detailed dietary feedback, and/or social comparison, for example. However, the effect on diet quality improvement that may occur through bringing perceptions more in line with reality should be explored by measuring diet quality and PDQ at multiple timepoints.

A major strength of this analysis was the measurement of PDQ using a 100-point scale in alignment with the range of the Healthy Eating Index. Additionally, to our knowledge, this is the first analysis to assess participants' perceived improvements in diet quality in a randomized trial.

A limitation of this analysis is that no PDQ data were captured at baseline or the interim 6-month timepoint as measurement began after many participants had completed the trial. Participants with complete data were significantly older and may have had better diet quality and improvements in diet quality than those with missing data. Having multiple assessments of PDQ may have allowed for an evaluation of how misperception at one timepoint may have affected subsequent diet quality and weight loss. Because of the small sample size, HEI calculation methods such as the bivariate and multivariate methods could not be utilized. Future studies may be needed to expand upon these results.

In conclusion, in this analysis of adults undergoing behavioral weight loss treatment, agreement between perceived and measured diet quality at 12 months was poor as was agreement about change in diet quality over the course of the intervention with many participants indicating better diet quality than measured. The HEI-2015 total score at baseline was less than the score of 74 which would meet Healthy People 2020 objectives.[39] Improvements in diet quality have been shown to relate to weight loss as well as weight loss maintenance.[204, 209] As diet quality was in need of improvement in this sample of weight loss-seeking adults, potential barriers and facilitators to diet quality improvement warrant investigation.

6.0 Discussion

6.1 Summary and Implications of Findings

The overall objective of this dissertation was to examine diet quality changes achieved through lifestyle modifications in trials targeting weight loss and to examine the relationship between diet quality change and cardiometabolic change and perception. Caloric restriction, which has been shown to be the most effective behavioral strategy for weight loss, has been the primary dietary focus of lifestyle interventions for cardiometabolic disease prevention.[213] Explicit goals for improving diet quality are limited in most programs despite diet quality being related to weight loss and weight maintenance as well as being important for cardiometabolic health independent of weight. As such, few programs track or report changes in the diet quality that result from program participation. Therefore, it is unclear if diet quality is improving in behavioral interventions and if so, how and why it is improving. Toward filling this gap in the literature regarding change in diet quality resulting from weight loss programs for cardiometabolic disease prevention, this dissertation comprehensively assessed evidence using a valid and reliable measure of diet quality in alignment with evidence-based dietary guidelines [i.e., the Healthy Eating Index (HEI)] and utilized recommended methods of calculating a diet quality score.

Our systematic review (*Manuscript 1*) found 18 behavioral RCTs with weight loss goals that assessed diet quality changes in line with US dietary guidelines. There was a great degree of heterogeneity in behavioral components, intervention length, study population, and other factors across studies. Several important findings from the review arose. First, it was clear that few studies planned to assess dietary changes. This was reflected in subpar dietary data collection and HEI calculation methods as well as poor description of such methods in the text of included studies. As a result, almost all authors needed to be contacted in order to confirm the HEI calculation method.

However, the most important result was that despite some studies reaching what is likely to be a meaningful improvement in diet quality, the diet quality improvements seen were small to modest. The authors of the included studies noted that these less-than-ideal results may have been due to the fact that improving diet quality was not a goal of their interventions. This would suggest the ability of behavioral interventions to alter diet quality has been largely untapped. It is unknown what potential diet quality improvements are achievable if 1) explicit diet quality goals were added to interventions, and 2) specific behavioral strategies for targeting diet quality were incorporated. Therefore, it is also unclear what strategies might best aid participants in improving their diet quality.

A similar review looking at both US and Canadian versions of the HEI and the AHEI has been conducted.[215] Only four studies in that review overlapped with studies included in our review. However, some findings were similar. For example, more intensive multicomponent interventions tended to relate to better outcomes, and there was a wide variation in the amount of diet quality improvement seen across studies. Also, both reviews recommended more research be done such that the effect of specific intervention components might be able to be assessed in the future with particular attention paid to methodological considerations and reporting (e.g., recruitment of subjects, calculation of the HEI).

Having assessed the state of the evidence for diet quality change in behavioral weight loss RCTs in Manuscript 1, the results of Manuscripts 2 and 3 could be better contextualized. For Manuscripts 2 and 3, this dissertation made use of data from the SMARTER RCT, which employed a mHealth intervention. By utilizing technology, such scalable interventions hold much promise for intervening with a large segment of the population unable or unwilling to engage in in-person standard behavioral treatment for weight loss.

Our analysis found that the provision of feedback to dietary self-monitoring did not result in larger improvements in diet quality compared to self-monitoring without feedback (*Manuscript 2*). The changes in diet quality in both arms were minimal. Thus, our results were similar to those seen in studies included in the systematic review.

In particular, our results were similar to other minimal contact interventions such as in the cellphone-based arm of the CITY intervention[238] and in a workplace intervention that included automated feedback.[268] A very similar internet-based weight loss intervention with energy and fat goals, self-monitoring, and automated feedback, showed slightly larger improvements (~4 points) but over a shorter timeframe.[241] Results may have been more similar if participants were followed up until 6 and 12 months.

The dietary pattern seen in our sample at baseline was fairly similar to that of the general population: maximization of the total and seafood and plant protein components, a near perfect whole fruit component score, and particular room for improvement in the moderation components of the index. Feedback messages largely did not address these moderation components of the diet. As saturated fats in particular contribute a large number of calories, feedback messages able to alter this type of consumption might be helpful for both diet quality improvement and weight loss. Similarly, messages addressing other moderation components, such as sodium, might have benefits beyond improving the diet quality score such as improving blood pressure. Future interventions utilizing dietary feedback might pay particular attention to these aspects of the diet.

Our SMARTER analysis by weight loss status revealed that those who lost a clinically meaningful amount of weight, compared to those who did not, had greater improvements in diet quality over the course of the intervention (*Manuscript 2*). The magnitude of improvement seen was likely meaningful. Our results expand on those seen in other trials such as in the Weight Optimization Revamping Lifestyle using the Dietary Guidelines (WORLD)[208] and Daughters and Mothers Against Breast Cancer (DAMES)[209] studies.

While the DAMES study was similar to SMARTER in that it involved no in-person component, ours may be the first mHealth intervention to show a relationship between weight loss and diet quality improvement. In a short-term 4-month pilot study, women who achieved clinically meaningful weight loss improved HEI-2005 total score by 8.3 points.[207] Although larger than the diet quality improvement we saw in SMARTER, our results at 6 months were retained at 12-months which is important as some weight regain is often seen after 6 months. [208, 230] Results from a study among rural breast cancer survivors who maintained lost weight (≥5% of baseline weight) at 18 months versus those who did not, point to the potential importance of diet quality improvement not only for initial weight loss but also for prevention of weight regain.[205] One major strength of our investigation compared to those others described here is that we observed a relationship between weight loss and diet quality change using the preferred Population Ratio method of calculation.[132]

Unfortunately, although close, we did not have sufficient numbers of participants with two days of intake of certain episodically consumed foods (i.e., fruit juice and legumes) to use the more robust bivariate[133] or multivariate[135] methods of HEI calculation. Because of this and because of the small changes in diet quality and cardiometabolic risk factors on average in SMARTER, we could not assess the relationship between diet quality change and change in cardiometabolic risk factors (e.g., weight, waist circumference, and blood pressure) as comprehensively as we would have liked. Future large studies might conduct analyses using structural equation modelling to examine such a relationship while considering changes in energy and physical activity. This would help quantify both the direct and indirect effects of diet quality improvement on cardiometabolic changes. Adding a third day of dietary data collection, increasing response rates, and having non-consecutive recalls and a mix of weekend and weekday recalls are steps that could be taken in future studies to attempt to attain data sufficient for such calculation methods.

Finally, in *Manuscript 3* we began to address possible reasons for a lack of meaningful improvement in diet quality among SMARTER study participants. The Theory of Planned Behavior[275] along with other theories/models/strategies (e.g., Health Belief Model, motivational interviewing[287, 288]) emphasize the importance of understanding psychological factors such as patient perceptions, beliefs, and motivations when attempting to change dietary behaviors.

Our findings suggest a mismatch between participants' perception of their diet quality and measured diet quality. Importantly, we found even more of a mismatch between participants' perception of their change in diet quality and measured change. To our knowledge, this is the first analysis of the relationship between perceived and measured diet quality in an interventional setting.

One plausible reason for discordance between perceived and actual diet quality may be knowledge of what is healthy. However, the relationship between knowledge of dietary guidelines and perceived and objective diet quality is unclear. A recent analysis among adolescents showed, contradictorily, knowledge of US nutrition guidelines related to both increased and decreased odds of healthful consumption. Adolescents' knowledge of the guidelines was not associated with perceived diet quality.[289] Among adults, NHANES data has shown a relationship between knowledge of nutritional guidelines (i.e., MyPyramid and MyPlate) and Healthy Eating Index scores[290] but not with perceived diet quality.[291] It is important to note that "knowledge" of the guidelines may represent little other than the knowledge that guidelines exist and that general consumption of certain foods (e.g., fruits) may be better than others (e.g., candy). Indeed, possible additional components such as in-depth discussion of nutrition with dietitians, understanding of servings sizes, practice of cooking techniques, tasting of new healthful foods and recipes, may be a more robust way of altering knowledge. This knowledge and practice might then relate to improvements in diet quality.

While bringing participant perceptions more in line with actual diet quality may seem an obvious target for future interventions, the outcome of such alignment may not be as predicted. As such, our findings should be replicated in other studies preferably with measurements of perceived and calculated diet quality at multiple timepoints.

The results of this dissertation are consistent with other reviews of the literature. Evidence that healthy food prescription programs improve diet quality and cardiometabolic risk factors is low to moderate suggesting a need for high-quality trials.[292] Too, while a review of smartphone applications for the promotion of healthy diet notes the potential for increased reach, it additionally notes that randomized designs, larger sample sizes, and longer follow-up are needed before conclusions can be drawn as to the effectiveness of apps for altering diet.[293] We too recommend additional high-quality research to fully understand the ability of behavioral interventions to alter diet quality.

6.2 Public Health Significance

The prevalence of adult obesity was 42.4% in 2017-2018 with many other US adults in the overweight range such that around 74% have overweight or obesity.[147] The diet quality of US adults is particularly poor among those with overweight and obesity.[41, 150] Poor diet quality is associated with weight gain,[148] and improving diet quality has been related to weight loss[207, 208] as well as weight loss maintenance.[204] Encouragingly, some studies see the biggest improvements among those with the worse initial diet quality suggesting feasibility for intervening in those most at-risk.[194, 294] Through diet quality's effect on obesity, the risk of developing type 2 diabetes, cardiovascular disease,[211] and cancer[212] may be reduced. This is important as heart disease, cancer, stroke, and diabetes are among the top 10 causes of death in the US.[295] Heart disease is responsible for 1 in every 4 deaths and about $363 billion yearly in health care costs and lost productivity.[296] In the US, 10.5% of the population has diabetes with another 34.5% in the prediabetic range.[297] Stroke is the leading case of long-term disability with reductions in mobility in more than half of stroke survivors over the age of 65 years.[296]

Dietary improvements would be projected to reduce the burden of disease significantly. As would be expected, simulated 2-quintile improvements in diet quality do not result in immediate, but accumulated reductions in diabetes, heart disease, and stroke prevalence of about 10% over 30 years which subsequently lead to fewer deaths and lower associated health care costs.[261] A 20% improvement in the average HEI-2015 diet quality score of U.S. adults would lead to cost-savings of approximately $31.5 billion in 2017 dollars.[298] These estimates are based on theoretical improvements in diet quality. Observed improvements in diet quality generally agree with projections. Over 12 years, combining data from NHS and HPFU, diet quality improvements have been associated with a decreased risk of death.[299]

With such a significant burden of morbidity and mortality due to chronic diseases such as these, major organizations like the American Cancer Society (ACS), specifically recommend healthful dietary patterns as the focus for health behavior change, as opposed to specific foods and nutrients. The ACS reason that the additive and interactive effects of multiple nutrients/foods may be more important for cancer prevention than the effect of any single food/nutrient.[1] The American Heart Association (AHA) has similarly recommended healthful dietary patterns for improving cardiovascular health,[2] and the American Diabetes Association (ADA) also has emphasized that various healthful eating patterns may be followed in the medical nutrition therapy provided to patients with diabetes and prediabetes.[3] A detailed overview of the relationship of diet to cardiovascular disease, diabetes, and obesity suggests that diet quality be a particular focus of clinical care, advocacy, research, and policy.[52] With over 900 articles published in 2018 on the topic of nutrition's relationship to cardiovascular disease, researchers are devoting tremendous resources to this research area.[26]

However, the public health significance of determining effective methods of diet quality improvement is supported not only by the burden of disease and interest of researchers and policy makers but also by the interest in nutrition by public. Americans are spending a great deal of time considering diet. The number of Americans on a special diet is increasing with a weight loss or low-calorie diets being the most common type of special diet. About 23.1% of Americans with obesity are on a special diet on any given day.[300]

The evaluation of diet quality change in weight loss interventions is necessary to inform this expanding field with six specific areas of future research needed. It is important to understand 1) what dietary changes can be achieved, 2) for how long, and 3) what are the barriers and facilitators to diet quality improvement. An effect of the lack of prioritization of diet quality improvement is that assessment of dietary changes has been relegated to secondary and exploratory analyses with dietary analytical considerations and methods poorly understood by researchers. Attenuation and lack of power are major challenges of analyses where change in diet is assessed because the variation in dietary change is usually less than the variation in diet observed cross-sectionally and because the change is based on baseline and follow-up measures of diet which both come with error.[10] Therefore, there needs to be better understanding and 4) standardization of the measurement and calculation of diet quality.

After this, we can begin to 5) evaluate the effect of adding specific behavioral components targeting diet quality to interventions. Because behavioral interventions have largely failed to demonstrate improvements in diet quality among high-risk populations even when improvements are seen for other outcomes, future research should focus on identification of behavior change techniques[301, 302] that would be conducive to improving diet quality. The Obesity Related Behavioral Intervention Trials (ORBIT) model[303] may be a particularly useful framework in which behavioral weight loss researchers might situate their interventions. Only then can we 6) assess how changes in diet quality relate to health outcomes in the interventional context.

6.3 Conclusion

Our results indicate that overall, the field has inconsistently assessed diet quality in behavioral trials across multiple settings. Changes seen in diet quality in these lifestyle interventions are small with additional room for improvement, but larger changes in diet quality do relate to clinically meaningful weight loss. Targeting diet quality is a feasible, and likely acceptable, way of improving the health of those with overweight/obesity. Perception of diet quality might be a particularly important facilitator/barrier to be addressed when intervening with participants who would benefit from more specific focus on diet quality overall. Given the ample cross-sectional and prospective evidence linking diet quality to weight status, weigh gain, weight loss maintenance and other non-weight related risk factors for chronic disease development, diet quality should be assessed as an important behavioral outcome of interventions with ultimate aims of preventing chronic disease development and progression.

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